A STUDY OF STRATEGIC OPPORTUNITIES FOR CANADIAN BIOTECHNOLOGY IN ANIMAL HUSBANDRY PRODUCTS

PHASE II REPORT

FOR

INDUSTRY SCIENCE AND TECHNOLOGY CANADA

BY

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SUMMARY & CONCLUSIONS

The department of Industry, Science & Technology (ISTC) seeks to identify strategic opportunities for Canada in the application of biotechnology to the animal sector. Deloitte & Touche was commissioned by ISTC to identify and qualify the most successful niche opportunity areas within animal biotechnology. An initial Phase I report identified 11 biotechnology mechanisms which could be used to develop products to address seven animal production objectives, such as improved productivity, feed efficiency, carcass quality and disease control.

Three product areas were selected from this significant array of alternatives for more detailed examination and qualification of their market potential, and product development and commercial marketing environments.

These product areas include:

- univalent and multivalent vaccines;
- pro-biotics; and
- immunization techniques for carcass quality

Identification of market potential incorporated a global perspective but with particular emphasis on North America, Europe and South American markets for animal biotechnology products. Key evaluation criteria involved in the product development environment involved consideration of:

i) the development time and cost associated with commercial development of prospective products;

ii) availability of Canadian based biotechnology and commercial exploitation potential in terms of resources;

iii) the window of opportunity for development and sustainability of competitive advantage in the product and commercial development areas;

iv) the potential commercial and financial benefits to Canadian biotechnology

companies, Canadian farmers and other industry participants;

v) the negative impacts of non-development of expertise and products in this area; and

vi) the socio-economic environment for product research, registration and use.

Evaluation of the market potential and product environment involved reviews and analysis of published and unpublished data and information on the specific market areas, and a series of discussions and consultations with biotech research and commercial industry participants.

KEY FINDINGS

Canadian Animal Biotechnology

Canada has a very limited presence in the commercial animal biotechnology sector. The commercial presence is largely oriented towards the vaccines component of the biotechnology markets and largely defined by the activities of Biostar (Saskatoon) and Langford Inc. (Guelph), now a subsidiary company of Cyanamid. While both organizations have had commercial success in the market, the real recognition and profile for these organizations comes from the underlying pioneering research and development activities at VIDO - University of Saskatchewan and the University of Guelph, and the support and involvement of the NRC in animal biotechnology. These organizations and supporting research and development infrastructure are considered to be at the leading edge of the development of univalent and multivalent vaccine technology. Canada has a much less visible and level of involvement in research development of beta agonists/partitioning agents, and virtually no profile and involvement in pro-biotic research and product development from a biotechnology perspective.

Market Opportunity for Animal Biotechnology Products

North American (32%), the EEC (23%), Eastern Europe (14%) and specific country areas of Brazil, Australasia and Japan are the primary market areas for animal husbandry products. These areas are characterized by having large livestock populations and a high level of commercial production. Additionally, they have high to medium levels of production technology use, livestock concentration and economic infrastructure to accommodate sophisticated animal health product use.

These latter two features are perhaps more influential in determining animal health product market than the former market features. For example, North America and the EEC account for more than half of the overall market of these products, but only account for approximately 20 percent of overall livestock populations.

North America's livestock production sector provides the largest, most accessible and consistent market for animal health and prospectively animal biotechnology products. The

EEC is the second largest market for biotechnology products, although market access is limited by the fragmented market structure, technology utilization, and language barriers. Additionally, market access for production enhancement products is becoming more difficult because of consumer and society attitudes towards a number of existing product categories and the requirement for socio-economic impact assessment for new product registration in these areas. Harmonization of registration requirements in 1992 may reduce some of the costs and technical difficulties of market entry to the EEC market, but it is unlikely to remove the socio-economic and structural barriers to market entry.

Selected opportunities exist outside these two primary market areas, although each market opportunity incorporates a number of barriers to market entry, including the level of technology use (Brazil), availability of hard currency to buy high-tech products (Eastern Europe), and production systems which do not lend themselves to animal health product use (Brazil & Australasia). (See Chart 1).

CHART 1 BARRIERS TO MARKET ENTRY - BY COUNTRY

COUNTRY	LIMITING FACTOR			TOTAL (scale 1-9) (lower # = fewer barriers)
	Currency	Production system	Available technology	
Canada	0	0	0	0
U.S.A.	0	0	0	0
Mexico	2	2	2	6
Brazil	2	2	2	6
Argentina	2	1	1	4
Australia	0	1	0	1
U.K.	0	0	0	0
Germany	0	0	0	0
France	0	1	0	1
East. Europe	3	1	2	6

0 = no limitations
1 = slight limitations
2 = moderate limitations
3 = severe limitations

High Efficiency Vaccines

There is a significant market opportunity for high efficiency vaccines and diagnostic products from biotechnology sources. The technology is known and understood, and Canada has a state of the art capability in this area. The animal health vaccines market is small and a low margin business relative to the human health sector. This particular feature has prompted several research and/or commercial animal health firms to drop their research activities in this sector or divest in favour of the human health market. A high degree of competitiveness plus difficulties in effectively patenting univalent vaccines has contributed to this market situation. Development of multivalent vaccines for addressing specific disease complex areas such as the respiratory disease complex in cattle provides a more attractive market opportunity since the combination of vaccine entities affords some commercial protection. Specific disease opportunity areas include shipping fever, BVD, IBR and baby pig scours (see Chart 2).

CHART 2

DISEASE	COST OF CONDITION		MARKET POTENTIAL	
	World	North America	World[1]	North America
Shipping Fever	3,000	500	800	125
BVD	1,750	250	800	50
IBR	2,500	300	800	75
Pig Scours	1,800	250	720	55

Competition in this area is stiff. Approximately 180 firms worldwide are active in the area of animal vaccines. Over 100 firms are active in the area of biotech vaccines. (See Chart 3)

[1] optimistic estimates

CHART 3 COMPANIES/INSTITUTIONS INVOLVED IN PRODUCTION/MARKETING OF LARGE ANIMAL VACCINES USING BIOTECHNOLOGY

COUNTRY	# OF COMPANIES/ ORGANIZATIONS
Canada	8
U.S.A.	113
Europe	34
Japan	1

* Some double counting as some companies are active in more than one country

Pro-biotics

Biotechnological development of pro-biotic organisms or the relevant substrates holds considerable potential. However, product development in the pro-biotic areas is not as advanced as in other biotec product areas, given continuing uncertainty as to the mode of action of pro-biotics. Additionally, mixed results in terms of performance of existing products, and difficulties in development and maintenance of viable products and delivery systems for pro-biotics, also contribute to uncertainty in this area.

Development and use of pro-biotics is still a fringe activity with only a few of the multi-national animal health product manufacturing companies showing commercial interest in this area. The high and uncertain costs of product development, an uncertain regulatory environment and an inability to compete effectively with sub-therapeutic levels of antibiotics as yet counterbalance the significant opportunity for pro-biotic products in animal agriculture.

Irrespective of the products' technical difficulties, the market for these products will still likely outpace the measurable economic value of their use and entrepreneurial companies will flourish, albeit with an uncertain future. Specific opportunities are likely to develop within integrated, branded or "natural" products where these products can be used to substitute for conventional feed additive products. The most likely initial market opportunity for this product category is in the EEC, given the market environment and the level of product research and development.

Canada has an exceedingly limited involvement in this area from an R&D perspective, commercial development and product usage activity. Our most important involvement is the existence of one of the most significant databases of microbial agents, compiled through Agriculture Canada.

Immunological Approach to Carcass Quality

Significant market potential exists for products which can change the carcass or product

quality aspects of food producing animals. For example, the low/lower-fat market for hogs and/or beef cattle in Canada alone is estimated to be worth $45 million. Similarly, low fat milk products market in dairy and the low cholesterol markets are also of major significance.

Immunology products are at the commercial development stage (eg., Somatostatin inhibitors), although the commercial introduction and adoption of these products incorporate some uncertainty given public opinion and attitudes towards use of similar performance enhancing products such as hormones and BST. Moreover, strong competition from conventional breeding technologies and possibly more direct and more sociologically acceptable competition from directly addressing fat and cholesterol issues from human biotechnology approaches will provide strong competition to animal biotec approaches. Additionally, research and product development in this area will be strongly influenced by research in human immunological systems and the weight of research spawned by AIDS. The weight of research activity in this area is vested in the U.S. and Japan. Canada has a small investment and capability in this area, relatively speaking, but is relatively well positioned given our strengths in the area of immunization for disease control. Chart 4 shows the number of companies in Canada involved in various biotech approaches to improving feed efficiency/carcass quality.

Overall Market Opportunities

Quality enhancement products and multivalent/univalent vaccine products provide the most attractive market areas. Markets for cattle and dairy products within these groups typically provide greater market opportunities (Chart 5).

CHART 4 NUMBER OF COMPANIES INVOLVED IN BIOTECH APPROACHES TO FEED EFFICIENCY

APPROACH USED	# OF COMPANIES/ORGANIZATIONS ACTIVE IN CANADA
Immunization Techniques	3
Other Animal Health (Antibiotics produced by fermentation)	6
Genetics	6
Hormonal	7
Feed	1

* Some double counting as some companies are active in more than one ~~country~~ area

Research and Development

Canada is perceived as having a positive research and development environment. Key components of this research and development environment include:

- a solid base of high calibre research scientists within university and government research institutions. A common perception was that research personnel had a broad or integrated understanding of animal production and other related issues;
- public sector facilities for product research and testing;
- high disease-free status of domestic herds;
- legislation which requires domestic research and development expenditure; and
- a continuing, relatively benign attitude towards animal research, relative to the European environment in particular.

This environment is strongly associated with a leadership position in development of vaccines rather than productivity enhancement products or pro-biotics.

Canada does not have as comprehensive a package of industry wide financial fiscal and legislative support as most Western Europe and Japan countries. The U.S. relies almost exclusively on private sector funding for research and development activities. A feature the U.S. approach tends to be is a focus on short term commercial product development. An example of this is a focus on diagnostics rather than vaccines.

Regulatory Environment

Canada's regulatory environment is generally viewed as positive by major animal health

product manufacturing firms. That is, the system is tough, fair, and in the main, science based with appropriate, well established protocols. Additionally, continuing efforts toward harmonization and acceptance of protocols between the U.S. and Canada is a positive feature of the Canadian system relative to those of Japan and, to a lesser extent, Europe. In some respects, U.S. individual research and development managers were more supportive of the Canadian regulatory authorities than their U.S. counterparts in terms of the fairness and equity of the system, particularly with respect of USDA vs. Agriculture Canada regulation of the vaccines sector. On the other hand, their Canadian counterparts had an opposite view.

There are concerns about potential areas of overlap or uncertainty with respect to jurisdiction over emerging product technologies, notably pro-biotics in the registration process between BVD (Health & Welfare) and Agriculture Canada. This uncertainty is perceived to have retarded the product registration process and provides a more uncertain environment for product research and development. Additionally, the ad hoc nature of Agriculture Canada's registration process could well be open to a range of socio-economic and other subjective influence in product registration.

An additional concern is the potential impact of the pricing component of Bill C22. That is, the pricing protocols may be inappropriate or unworkable for new and emerging product technologies and, hence, limit the marketing or market opportunities of these products in Canada. In addition, concern is that biotechnology products may not be patentable and/or that patents may be unenforceable, particularly with vaccines and pro-biotics.

OPPORTUNITY AREAS

Development of Commercial Vaccine Products

Development of high efficiency and particularly multivalent vaccines has significant short term and long term potential benefits to the Canadian biotechnology firms. The

technology is well understood; there are significant market opportunities, particularly within the large scale and accessible North American market in both the cattle and hog sectors, and Canada has a state of the art capability and commercial lead in some of the specific opportunity areas.

Development of Companion Delivery Systems

A companion opportunity in this and other biotechnology areas is in development of delivery mechanisms. Much of the research focus is on the primary control, or impact of a particular product rather than on development of effective delivery systems which can provide an additional commercial advantage for the primary product. Specific delivery system opportunities are directly related to the overall market opportunities.

Market of the Canadian Research & Development Environment

The Canadian research and product development environment has a number of positive features which it could incorporate into an overall strategy for marketing biotechnology research and development in Canada to organizations outside North America, viz:

i) a strong state of the art basic research capability in biotech;

ii) a supportive university and government research infrastructure;

iii) proximity and access to the U.S. market;

iv) a more benign research environment in Canada relative to Europe;

v) the health status of Canadian livestock;

vi) a tough, fair scientifically oriented regulatory environment; and

vii) a significant domestic agricultural industry with similar production systems in markets of high commercial potential.

There are perhaps no specific unique commercial opportunity areas (significant, North American disease areas) which are not being addressed by some research agency in North America. The specific opportunities are tied to areas of major commercial significance and areas where Canada has a scientific or commercial lead. These areas would include:

- shipping fever
- BVD
- IBR
- haemophilus pneumonia

Commercial Product Acquisition

A corollary of the above strategy would be to pursue commercial access and/or licensing agreements for product inventions developed outside Canada. In this regard, Japan is perceived as having a research oriented and human health oriented biotechnology development program which can spawn significant commercial products for the livestock sector (IVERMECTIN, for example: the world's largest single animal health product in monetary terms, was developed in Japan but marketed by MSD Ag Vet). Consequently, Japan would be an appropriate initial focus for such activity.

Barriers & Threats to Commercial Animal Biotechnology Development

Commercial biotechnology development is heavily dependent on the base intellectual raw material and supporting infrastructure. While Canada has a strong foothold in the animal biotechnology research world, it does not have the resources or market power of the United States. Ensuring that Canada is competitive in selected areas of excellence is a prerequisite for development of an appropriate animal biotechnology research and development industry.

Like most commercial activities, access to specific markets and commercial success in those markets is typically easier to obtain if an organization has a realistic research, development and commercial presence within a particular market place. This condition is perhaps more critical in highly regulated industry sectors where ad hoc procedures exist

for product registration. Consequently, for a Canadian entity to be successful in a North American context it would be extremely beneficial for a Canadian organization to have a commercial base in the U.S. or an appropriate strategic linkage with a U.S. organization. This will undoubtedly require Canadian investment in U.S. research and commercial product development activities.

The socio-economic and political environment surrounding a country or region can significantly affect research and development investment activities, product introductions and use within specific markets. This feature not only may have an effect on the animal biotechnology sector, it can also have a significant subsequent effect on the competitiveness of the domestic agricultural industry. A pro-active and long term program to ensure that the socio-economic environment does not adversely affect legitimate research and commercial market opportunities may be necessary.

Application and advantages in conventional technologies viz, breeding, feeding and veterinary medicine and farm management practices continue to provide significant rates of productivity and carcass quality improvements in the livestock sector. While perhaps less dramatic, they pose strong competition to biotechnology development. In the case of breeding technology, in particular, the benefits to the returns to investment in genetics, may outweigh investment in novel biotechnologies for productivity improvement and carcass quality advancement, both in terms of the genetics industry and the domestic production sector.

1.0 INTRODUCTION

The Department of Industry, Science and Technology (ISTC) seeks to identify strategic opportunities for Canada in the application of biotechnology to the animal husbandry sector.

The National Biotechnology Advisory Committee (NBAC) advises the Minister of Industry, Science and Technology on ways and means of using biotechnology to develop and maintain the competitiveness of Canadian industry. Recently the NBAC has established three Working Groups to address different aspects of biotechnology growth in Canada. One of these, the Working Group for Agribusiness and Food has determined, through a preliminary survey of companies prominent in the Canadian agriculture and food sectors, that opportunities for growth might be found in the development of improved veterinary products. It is anticipated that these opportunities will lie mainly in two areas. One of them is in the development of genetically engineered vaccines for the treatment of endemic diseases of large animals. The other is in novel hormonal treatments for improved feed efficiency and utilization, and faster more productive animal growth.

Consequently, Deloitte & Touche has been commissioned by ISTC to identify the most significant niche opportunities for biotechnology based development within the animal husbandry area.

The approach used to incorporate an initial research phase to gain a broad overview of the issues affecting the competitiveness of the Canadian industry. A report on the first phase was submitted in June, 1990. The specific objectives of this initial research were:

1. to identify and list the major issues/products/techniques of significance to the biotech industry; and

2. to provide an initial assessment of the commercial significance of these areas and desirability of further research.

This document reports on the next phase of the research, and further investigates opportunity areas for Canadian products, and Canada's competitive position vis a vis number of market, technical, financial, and institutional factors.

2.0 STUDY BACKGROUND AND OBJECTIVES

2.1 Study Background

The Phase I report documented eleven mechanisms through which biotechnology may be used to develop products for the animal husbandry industry. These are:

1. sub-unit vaccines;
2. univalent live vehicle vaccines;
3. multivalent live vehicle vaccines;
4. monoclonal antibodies;
5. anti-ideotypic antibodies;
6. rapid detection systems/diagnostics;
7. chemical metabolic regulators;
8. modified microbes (internally applied);
9. modified microbes (externally applied);
10. transgenics;
11. enhanced embryo transfer techniques.

Products manufactured using these mechanisms may be directed towards addressing a number of animal husbandry issues. These issues were defined in the report as:

1. improved productivity;
2. improved feed efficiency;
3. alternative feed use;
4. altered product composition;
5. improved carcass quality;
6. reproductive management; and
7. disease control/animal health.

Following the review of the Phase I report it was determined that three topics in particular should be the subject of the Phase II research. These three topics are:

1. Uni- and Multi-valent vaccines;
2. Products which improve feed efficiency; and

3. Products which improve carcass quality.

While vaccines represent a defined "product", the issues of feed efficiency and carcass quality require further qualification. Either of these areas may be approached by an almost unlimited number of potential techniques. For example, biotechnical approaches may be applied to improving feed efficiency in the following ways:

- altering metabolic pathways through immunological or chemical means;
- microbial enhancement of feeds;
- transgenic manipulation of the genome to obtain or enhance desired traits; and
- enhancing the reproductive capability of animals which are already superior in the desired traits.

These examples are highly simplified. Indeed, each of the four approaches could be further subdivided into as many specific approaches as there are determinants for each specific issue.

In order that this report be as specific and useful as possible given finite resources, the investigations will focus upon means of achieving enhanced feed efficiency and improved carcass quality through biotechnical processes which are technically feasible at this time or are expected to be in the near (1-5 years) future. In the case of the issue of feed the specific "products" to be examined are immunization techniques and probiotics, given an initial assessment of their state of development and market potential.

For the products defined about, the specific objectives of this Phase of the research are:

1. Determine the market size in volume and value terms of potential markets for these products in North America, South America and Western Europe.

2. Identify the competitive and regulatory environments surrounding the development of animal husbandry products in these areas.

3. Qualify the development potential of opportunity areas in terms of:

i) the development time and cost associated with commercial development of prospective products;

ii) availability of Canadian based biotechnology and commercial exploitation potential in terms of resources;

iii) the window of opportunity for development and sustainability of competitive advantage in the product and commercial development areas;

iv) the potential commercial and financial benefits to Canadian Biotechnology companies, Canadian farmers and other industry participants; and

v) the negative impacts of non-development of expertise and products in this area.

2.2 Competitiveness Framework

The objectives listed in the preceding section will be addressed through a two step process. The first step is a situational analysis, wherein the various factors affecting the biotech animal husbandry sector will be qualified and quantified. The second step is a competitiveness assessment, wherein a profile of the competitiveness of specific product areas will be detailed and assessed vis-a-vis key competitors.

3.0 GLOBAL MARKET OVERVIEW

3.1 Introduction

This chapter provides an outline of the livestock situation within regional markets for animal husbandry products within a global context. The potential commercial market for animal husbandry products within any region or country is dependent on a number of features. Livestock numbers, and/or commercial production levels are obviously a basic ingredient of commercial market potential. Moreover, the ability to absorb, use and benefit from high technology animal health products is dependent on an appropriate level of supporting technology and output.

These basic elements are accompanied by an extensive range of features which influence the market for animal health products. This list includes, but is not limited to:

i) the disease and health status of livestock populations

ii) the type of production and management systems: for example, intensive versus extensive production systems

iii) production economics and marketing infrastructure for specific livestock groups

iv) socio-economic and political infrastructure

v) consumer and producer attitudes towards animal food products and related production systems, and

vi) the size, structure, trends and competition within existing markets for animal health products.

An initial assessment of the relative size and attractiveness of specific markets from a technology perspective for the beef, dairy and swine markets is provided.

A more detailed qualification and assessment of the cattle, dairy and hog markets is provided for selected countries with more than 10 million cattle, 1 million dairy cows and 5 million hogs.

The analysis base for livestock numbers was taken from the annual Production Yearbook, published by the Food and Agriculture Organization of the United Nations (FAO), and The United States Department of Agriculture publication "World Livestock Situation". The most current editions at the time of writing provided data for 1988. These sources have some significant limitations in terms of absolute accuracy but they are consistent and serve the purpose of providing an assessment of the relative size, and guide to perspective market potential of the major livestock producing countries in the world.

The level of technology was evaluated indirectly from the available productivity data. In the case of dairy, milk yield per cow is a reasonable indicator of the level of industry sophistication, with a higher yield presumably resulting from a greater use of available technology and appropriate economic environment. For meat-producing animals such as pigs and cattle, the most commonly used measure of physical productivity is feed efficiency, or the rate of gain per unit of feed intake. This type of data is not readily available, given the large number of the world's animals which are range-fed or pastured. (Consumption data is not available.) Consequently, productivity levels in the beef and swine markets were assessed on the basis of the ratio of the total meat production per head of inventory. While there are obvious limitations to this methodology such as failure to account for different breed types, it is an appropriate proxy given the database available.

The level of technology was determined through contact with international agriculture specialists within Deloitte and Touche, and through data prepared by the FAO. The level of technology is defined as the use, and availability of modern animal health products and supporting services, including veterinarians.

Table 3.1 **Cattle Production (countries over 10 million head)**

Region	Inventory (x1000 head) 1988	Production (x1000 tonnes) 1988	Production Ratio (Kgs/hd)	Level of Technology
World	1,026,064	45,331	44	
N.C. America	145,863	13,607	93	
Canada	10,863	973	90	high
Mexico	35,378	1,754	50	low
USA	99,622	10,880	109	high
South America	190,579	6,445	34	
Argentina	50,782	2,610	51	moderate
Brazil	98,335	2,500	25	moderate
Colombia	18,400	707	38	low
Uruguay	10,306	321	31	moderate
Venezuela	12,756	307	24	moderate
Asia	371,325	2,343	6	low
Europe	128,910	10,722	83	
France	22,803	1,780	78	high
Germany FR	15,627	1,609	103	high
Poland	10,774	702	65	low
UK	12,695	990	78	high
Oceania	31,357	2,095	67	
Australia	23,500	1,533	65	high
USSR	120,593	8,465	70	moderate

Source: USDA, 1988

3.2 Beef Markets

The inventory of beef cattle worldwide is estimated at 1 billion (Table 3.1) with annual production of 45 million tonnes of beef. The largest concentration of cattle are in Asia and South America (Table 3.2) although production is concentrated in North America and Europe.

Table 3.2 Cattle Inventory and Production Concentration

Inventory (%)		Production (%)	
Asia	37	North America	30
South America	19	Europe	24
North America	15	USSR	19
Europe	13	South America	14
USSR	12	Asia	5

Some fourteen countries have more than 10 million cattle and a significant productivity level, including Canada. Of these, six have a high technology rating, five a moderate technology rating, and three a low technology rating.

The most important beef sector markets are the United States, Brazil, Argentina and the E.E.C. The E.E.C. and The U.S.A. are both large markets with a high degree of technology. Brazil and Argentina, although are low on the productivity scale, cannot be ignored as a potential market due to the large number of animals involved (149 million). Australia is also a significant player. Some qualitative factors which affect specific beef sector markets are as follows:

- USA

The United State represents the largest prospective market for animal health products in the beef sector, due to a combination of factors including:

1) a large beef animal inventory, second only to the USSR in terms of total numbers;

2) a high level of available technology and supporting systems such as veterinarians and facilities for administering and monitoring treatment of animals.

3) a strong industry concentration. That is, the production sector has large scale units and communication between all sectors, cow-calf, backgrounding, and finishing is excellent compared to most other countries; consequently, the dissemination rate of information on new products and management techniques is extremely rapid in comparison to other markets of similar size.

While beef consumption and cattle numbers have declined somewhat in the U.S., the U.S. is still the largest importer of beef products in the world. This suggests that American producers cannot fulfil their domestic demand. An analysis of returns to the beef sector suggests that high costs relative to other major producing and exporting countries, and a demand for "low grade" grass-fed beef are the primary reasons for this. Therefore, the market for products which improve efficiency of production and possibly products which could tailor domestic animals to meet consumer tastes would have significant potential.

- Western Europe

When considered as one market, the E.E.C. is almost as large as the U.S. in terms of cattle numbers. However, there are a number of factors which tend to qualify the overall market potential of the Community. These are:

1) diversity within the market. While harmonization is taking place with regard to regulation, there are significant differences in terms of management approaches and practices. In addition, disease and management issues can differ widely from country to country, and language barriers can make communication more difficult;

2) the size of operations is smaller, and higher subsidy levels have tended to encourage less efficient production, hence, there is less incentive to adapt new techniques;

3) beef production is largely an off-shoot of the dairy sector. Approximately 80% of the beef production is from the dairy breeds;

4) there is considerable consumer resistance to the use of "growth hormones" and other "additives". This issues is not restricted to the beef sector alone, but applies to all animal production.

In terms of individual country markets, France, Germany and the U.K. stand out. All of these countries have a relatively large production sector, as well as access to the latest technology. While France is the largest of the three, it is probably the smallest market overall for high value products, because farm sizes tend to be very small, and have a lower level of technology adoption in the sector.

- Brazil and Argentina

These two countries together account for some 15% of total world beef cattle numbers. Beef production in these countries is characterized by large, land extensive operations with lower than average production when compared to most industrialized countries. The market potential for high value products is constrained by the nature of extensive production, lower management levels, and cost considerations. Within both of these countries there are two definitive levels of production. Each country has put considerable effort into developing a nucleus of high technology production utilizing imported genetics and modern management techniques. However, output from this sector is a fraction of the total, and given the current unstable economic situation, particularly the lack of hard currency, the future of the present production and technology is in some doubt.

- Australia and New Zealand

These two countries account for almost half of the world's beef exports. Production, particularly in Australia, is characterized by large, specialist but extensive operations. Overall productivity, low compared to the U.S. and Canada, is the result of a more

extensive use of pasture as opposed to confinement systems. Cattle herds in Australia have declined since the mid 1970's as a result of fluctuating climates and severe droughts, and reduced access to European markets. In New Zealand, production also has declined as producers have had to accept lower prices for their products since losing major markets within the E.E.C.

This region represents high potential for animal health products due to the relatively large number of animals, and high level of management, as well as excellent supporting mechanisms and communication within the industry.

3.3 Dairy

The inventory of dairy cows worldwide is estimated at some 222 million head with production of 468 million tonnes of milk (Table 3.3).

While Asia (24%), Europe (21%), USSR (19%), South America (13%), Africa (12%) and North America (9%) represents the distribution of dairy cow inventory, Europe (37%), USSR (23%) and North America (18%) command the concentration of dairy production activities.

Twenty-three countries had inventory levels of more than 1 million cows, excluding Asia and Africa. Of these, seven had high technology ratings.

The USSR, United States, Brazil, and selected EEC countries have the highest numbers of dairy cows. However, Brazil and the USSR have much lower yields and technological levels than North America and Western Europe. Within Europe, France is the largest supplier of dairy products, but is less productive than most of its EEC counterparts. The Netherlands, West Germany and the U.K. are important markets when their level of production and technology are considered.

Table 3.3 Dairy Production (countries over 1 million milk cows)

Region	Inventory (x1000 milk cow 1988	Milk Yield (kg/cow) 1988	Production (x1000 tonnes) 1988	Level of Technology
World	222,003	2,110	468,362	
Africa	26,104	480	12,523	low
N.C. America	20,767	4,102	85,184	
Canada	1,437	5,674	8,150	high
Mexico	6,400	1,188	7,600	low
USA	10,243	6,444	66,010	high
South America	28,535	1,020	29,119	
Argentina	2,830	2,279	6,450	moderate
Brazil	18,100	729	13,200	low
Colombia	3,400	950	3,230	low
Venezuela	1,270	1,217	1,545	low
Asia	54,218	900	48,820	low
Europe	45,922	3,758	172,557	
Czechoslovakia	1,788	3,894	6,963	moderate
France	9,237	2,978	27,510	moderate
German DR	2,003	4,594	9,204	low
Germany FR	4,920	4,874	23,978	high
Ireland	1,444	3,784	5,463	moderate
Italy	3,020	3,599	10,869	moderate
Netherlands	1,940	5,832	11,315	high
Poland	4,940	3,121	15,420	low
Romania	2,000	2,150	4,300	low
Spain	1,747	3,789	6,620	moderate
UK	3,052	4,909	14,981	high
Yugoslavia	2,595	1,811	4,700	low
Oceania	4,456	3,189	14,209	
Australia	2,210	2,850	6,298	high
New Zealand	2,194	3,578	7,850	high
USSR	42,000	2,523	105,950	

Source: FAO Yearbook, 1988

While dairy and beef both deal with the same species, there are significant differences in terms of the potential products to be directed to each sector as identified in the following assessment:

- U.S.A.

Average milk yields per cow in the U.S. are the highest in the world. These high yields are a result of a number of factors including an economic system which places large rewards on productivity. This, combined with the fact that the U.S. dairy sector is second only to the U.S.S.R. in terms of total production, makes it the largest single market for dairy related products.

When compared to the beef sector, the dairy sector in the U.S. is somewhat more diverse in terms of regionality of production, and size of operation. Dairy production is typically located more closely to the end market for fluid dairy products; hence, the concentrations of production in California, the northeast, and the midwest. Wisconsin is the largest state in terms of both cattle numbers and total production.

Intensity and efficiency of production differ significantly across the nation. California herds tend to be much larger, produce more milk per cow, consume more grain per cow, and consume fewer pounds of grain per pound of milk produced. Indeed, across the United States there are variations between states of up to 50% in terms of efficiency of production per cow and per unit of grain fed. These differences may mean that individual products may have differing market potentials in terms of geographic application and market size.

- Western Europe

Dairy and dairy products are the single most important commodity in the E.E.C. accounting for 19% of all revenue in 1985. In individual countries the percentage of total agricultural production from milk varied from a low of 9% in Greece and 12% in Italy to 35% in Ireland and 26% in Germany. Average herd sizes differ significantly. In the U.K. 49% of the herds and 78% of all cows are in herds of over 50 animals. In contrast, in Germany 72% of the herds, and 40% of all animals are in herds of less than 20 animals, while in Greece, more than half of the cows in the country are in herds of less than 5

animals.

Milk yields per cow are also significantly different from country to country. The Netherlands, the U.K. and West Germany were above the E.E.C. average, while France, Italy and Ireland were below. Yields per cow are excellent indicators of the relative market potential for high technology products in Western Europe. While the U.K. and Germany differ greatly in terms of average size of operation, the management ability, genetic potential, and technological capability are similar, leading to similar production per animal. France, on the other hand has herd sizes similar to, or slightly larger than Germany, but average production per cow is much less.

Market potential for biotech products in the E.E.C. will vary by country. Products which do not require economies of scale in application, and which require little technological understanding on the part of the herd manager will have more universal appeal. Products which require higher levels of management will have greater potential in the U.K, Netherlands and Germany, and products which have any economies of scale when applied to larger operations will have the most potential in the U.K. and the Netherlands.

One of the most important considerations in addressing the European market for animal health products, particularly in the dairy sector, is the issue of socio-economics. New products, both conventionally and biotechnologically derived have come under intense scrutiny as to their potential impact on animal welfare, consumer health and the farm sector. Bovine Somatotropin (BST) is a classic example. It currently faces difficulties in getting registered because of the perception that:

1) as a "synthetic hormone" it may be harmful to consumers;

2) it may be harmful to the cattle, because of increased stress on the animal;

3) it may put smaller producers at a disadvantage in relation to large scale operations; and

4) it is output enhancing in a market system where there is significant overproduction.

E.E.C. regulations currently stipulate that a full socio-economic assessment be done as part of the basic registration package before any product may be licensed for general use or distribution. This significantly increases the cost, risks and likely time requirements for product registration.

3.4 Swine

The world inventory of swine and production of pig meat is estimated at 741 million head and 62 million tonnes respectively (Table 3.4).

The United States, in terms of individual countries and the EEC dominate the market in terms of production and productivity in the swine market. Asia, and the U.S.S.R. have large numbers of animals, but operate at a significantly lower level of technology, based on the recorded productivity of the national herds. In addition, the lack of infrastructure, and hard currency severely limit their potential as markets. Latin America produces significant quantities of hogs, and within Argentina, Brazil, and Venezuela there exists a nucleus of producers with excellent facilities and ability to use modern technology. These countries are severely limited by a lack of foreign currency to buy high value products manufactured outside of the country.

Canada enjoys the best health status of any major swine producing nation. In addition, the type of production practised in Canada (management intensive, confinement system) is practised in few areas of the world outside of North America, and northern Europe. Therefore, products which will have a domestic market may not be feasible in many other large hog producing countries for technical reasons, and conversely, for many products for which there is a large world market; for example parvovirus vaccines, there is no domestic market.

- <u>U.S.A.</u>

The U.S.A. is once again the most significant market for swine related animal health products. While the U.S. has a significantly smaller swine breeding than China or the U.S.S.R., the higher productivity of the sector does much to close the gap. For example, China has a breeding herd of almost seven times the size, yet produces less than three

times as much pork.

Table 3.4 Hog Production (Countries with over 5 million hogs)

Region	Inventory (x1000 head) 1988	Production (x1000 tonnes) 1988	Production Ratio (Kgs/hd)	Level of Technology
World	741,448	62,200	84	
N.C. America	78,011	9,266	122	
Canada	10,748	1,188	111	high
Mexico	10,879	964	89	low
USA	54,384	7,114	131	high
South America	37,258	1,379	37	
Brazil	31,700	1,100	35	low
Asia	358,446	23,728	66	low
Europe	188,065	20,996	112	
Belgium-Lux	5,958	813	136	high
Czechoslovakia	7,235	938	130	low
Denmark	9,048	1,168	129	high
France	11,915	1,599	134	high
German DR	12,503	1,414	113	low
Germany FR	23,670	2,838	120	high
Hungary	8,216	985	120	low
Italy	9,383	1,269	135	moderate
Netherlands	14,226	1,632	115	high
Poland	19,605	1,845	94	low
Romania	15,224	840	55	low
Spain	16,941	1,722	102	moderate
UK	7,915	1,048	132	high
Yugoslavia	8,323	819	98	low
Oceania	5,365	341	64	high
USSR	77,403	6,476	84	low

Source: USDA, 1988

Hog production in the U.S.A. and Canada is similar in many ways. The majority of U.S. production takes place in the North Central states under similar climatic conditions as in Canada, and utilizing identical feedstuffs (corn and soybeans). The structure of production is relatively similar, although there is a tendency towards larger scale operations than would be found in Canada. The major differences between the U.S. and Canada are: 1) there are different disease pressures (both parvovirus and pseudo-rabies are undergoing in the U.S.; 2) there is more vertical integration in the U.S. Feed companies and meat packers both play a larger role in hog production compared to Canada; and 3) the marketing system in the U.S. responds to somewhat different signals. Essentially, Canadian producers are paid for their product based on the relative amount of lean meat on the carcass. Americans tend (some packers base payment on grade) to get not paid directly for improved quality. Therefore, American producers may be somewhat slower to adapt products or techniques which improve leanness unless there are concurrent benefits in terms of growth rates or feed conversion.

- Western Europe

Four countries in Western Europe offer significant potential for high value swine husbandry products. These are: the U.K., the Netherlands, Denmark and Germany. Each of these countries is advanced technically, and possesses significant numbers of animals grown under confinement conditions similar to those in Canada.

When compared to dairy or beef farming in these countries, hog production is particularly concentrated. With the exception of Germany, the largest 25% of farms produce more than two thirds of the hogs.

Productivity, relative to the size of the breeding herd is also higher in Western Europe than in North America. This higher productivity is largely a result of superior genetics and intensive management practices.

The European swine sector suffers from some of the drawbacks which affect other European livestock sectors as a market for new biotech products. The use of growth hormones has come under severe scrutiny by both animal welfarists, and the consuming public. In addition, animal welfarists have succeeded in changing the way in which

animals are raised in several countries. In Sweden, legislation exists which outlaws the use of farrowing and gestation crates. All sows must be bedded on straw or shavings. This policy may have several impacts regarding animal health. First, lowered stress levels may reduce the need for sub-therapeutic levels of antibiotics, and second, there may be increased demand for products which could be perceived as welfare enhancers.

In summary, key markets for technologically advanced products, based on generic market size and by technology level, are as follows:

Chart 3.1 Regions of High Market Potential for High Technology Products

	BEEF	DAIRY	SWINE
1.	USA/Canada	USA/Canada	USA/Canada
2.	France/Germany/UK	Germany/UK/Netherlands/ France/Italy/Spain/Ireland	EEC (Total)
3.	Australia/Brazil/Argentina	Australia/NZ	USSR/E. Europe
4.	USSR	USSR	

4.0 ANIMAL HEALTH PRODUCT MARKET OPPORTUNITY

This chapter provides a description and, where possible, quantifies the potential commercial markets for animal husbandry and biotechnology products. Additionally, the state of the art of some selected product development and their market potential and ramifications are considered in this section. Specific consideration is given to the area of vaccines and to probiotic and immunology products for feed efficiency improvement and carcass or product quality enhancement in cattle, dairy and swine species.

4.1 Market Overview

The animal health and biotechnology research community is emerging from a period of euphoria and high levels of expectations with respect to the market potential for animal health and biotechnology products. New developments and discoveries in animal health products and the biotechnology capabilities certainly hold considerable market potential. However, difficulties encountered in bringing commercial products to market, changing attitudes of consumers and producers to high technology livestock production, and more realistic estimates of market potential and market penetration have lowered some of these euphoric expectations. It is unlikely that predictions of taking an overall animal health product market of approximately $8 billion in 1986 to $70 billion by the mid-nineties will be achieved. Nevertheless, it is a growth market, particularly the biological and therapeutics sector. Products such as BST and related products could add incremental growth of $500 million each to this market. Similarly, some new vaccines and/or diagnostic products could reach this potential. However, the commercial development and adoption are not instantaneous. BST, for example, would likely take up to 10 years to reach full market development even within a North American context.

The overall market for animal health products of some $7.7 billion is distributed across North American (32%), Western Europe (23%), and Eastern Europe (14%). Within this, overall market nutritional supplements and additives, performance promoters, biological products, and antibacterial agents accounted for 3.9 billion dollars in 1986. The distribution is as follows:

Nutritional Products	$1.3 billion
Performance Promotion	$0.7 billion
Biological Products	$0.7 billion
Antibacterial Agents	$1.2 billion

Estimates of relative growth rates are mixed. Nutritional products and conventional performance promotion products are seen to have limited growth potential, given competitive forces in the market, changing regulatory environment and patent expiry. Growth potential in the biological and antibacterial markets is seen to be very strong (15 to 20 percent per year).

Distribution of these markets by livestock species indicates that ruminants, swine and poultry dominate the overall market, although the pet sector is a strong component of the biologicals, and to a lesser extent, the antibacterials market. The estimated distribution of market size at manufacturer level is as shown in Table 4.1.

Table 4.1 Distribution of Market Size by Livestock Type in 1986

Product Class	Ruminants	Swine	Poultry	Horse	Pet	Dist.
	----------% of total expenditure----------					
Nutrition Products	18	13	9	1	1	42
Performance Promotion	2	12	2	-	-	14
Biological Products	5	2	4	-	3	14
Antibacterial Products	16	5	5	-	2	28
TOTAL	41	31	20	1	5	100

Source: Vivash & Jones

The information on existing product use shows the significance and importance of the North American and Western Europe on markets relative to the size of the overall total market potential based on livestock numbers.

While these markets hold the most immediate potential for high technology animal health products, some growth in demand for animal health products generally is likely to come from the rest of the world, given the relative rates of population growth and growth in demand for meat.

4.2 Market Potential for Selected Biotechnology Products

In approaching the market potential for vaccines, feed efficiency and carcass quality enhancement products, a number of components are included. In each sector a synopsis of opinion on the state of the art and focus of research of senior research and development personnel or commercial managers of major animal health product manufacturers is included (see Appendix 4.1 for list of manufacturers represented).

In the vaccines sector estimated costs of selected disease or animal health problems and indicators of market potential have been identified. For the products promoting feed efficiency/growth or producer quality enhancement specific examples drawn from in-house research background and through discussion with industry research scientists and other market estimates.

One of the most important and difficult aspects of this exercise is to estimate the degree to which a product would be used. It is not good enough to simply know how many animals there are which may be able to use the product. The rates and level of adoption depend upon several factors related to both the specific product, and the environment within which the product will be used. (The components of the classic adoption/ diffusion evaluation model are shown in Appendix 4.2).

This model is incorporated in the assessments made for the major product categories. It should be recognized that most of the products discussed are at a very preliminary stage, and all details of the product and delivery system have not yet be worked out. Thus, estimates of adoption are subject to considerable revision.

4.3 Vaccines for Disease Control Market

Live vehicle sub-unit vaccines are produced when the molecule (sub-unit) needed to elicit an immune response (antibody development) is transferred from the pathogenic organism (virus, bacteria or parasite) to an innocuous organism which can act as a carrier (this organism may also be a virus or bacteria, but one with no pathogenic properties). The resulting organism is then able to replicate itself as a means of producing the product.

There are two major benefits to a live vehicle sub-unit vaccine. First, the vaccine can be more efficient and effective, as only the specific antigen necessary to fight a particular disease is present, thus causing fewer side effects. Second, it is theoretically possible to use a single virus or bacteria to exhibit a number of antigens. thus a multi-valent vaccine could be produced. Through a single vaccination, a number of diseases could be controlled, or so could complex diseases, such as shipping fever, which have several vectors.

1. State of the Art

Senior research and development managers of major animal health product manufacturers felt that there had been tremendous or dramatic advances made in vaccine development and diagnostic capability in the last five years. Antigenic units had been identified in most areas and scientists and industry understand the technology, its capability and the requirements for further development. Development work on expression systems and adjuvants are needed. They also felt that the safety aspects associated with the high efficiency vaccines were the most

Table 4.2 **Estimated Annual Cost of Selected Animal Diseases and the Market Potentials for Recombinant Vaccines and Interferon**

	COST OF CONDITION (millions)			MARKET POTENTIAL* (millions)		
CONDITION	WORLD	U.S.	EUROPE	WORLD	U.S.	EUROPE
Feline Leukemia	$ 350	$ 75	$ 75	$ 500	$ 100	$ 150
Shipping Fever	3,000	500	375	800	125	90
Bovine Scours	1,750	250	200	800	125	90
Pseudo-rabies	650	60	75	720	55	70
Mastitis	35,000	5,400	3,500	800	125	90
Swine Parvovirus	1,600	225	250	720	55	70
Baby Pig Scours	1,800	250	275	720	55	70
Coccidiosis	1,800	300	275	600	120	110
Fowl Cholera	200	30	27	600	120	110
Foot & Mouth	50,000	--	--	2,500	188	175
TOTAL	92,800	6,515	4,592	8,760	1,068	1,050

Source: Office of Technology Assessment: 1988

* Market potential of veterinary practitioner's sales.
Costs for pet products are based on $2.00 per unit.
Costs for livestock products are $1.00 per unit, except interferon for shipping fever, which is $1.35.
Costs for poultry products are 3¢ per unit.

important feature, perhaps even more important than the vaccines themselves.

The problem areas associated with commercial development of univalent and multivalent vaccines revolved around:

- getting products from the lab shelf to the market, and
- the relatively small commercial markets and low margins or return on investment in the animal health vaccine markets, relative to the human health market.

Nevertheless, significant market potential existed and consequently the focus of research was on bovine, swine and poultry respiratory diseases (bacterial and viral), specifically shipping fever, pneumonia, haemophilus pneumonia, IBR, rhinitis, BVD, mastitis, and foot and mouth (Third World). Pseudo-rabies and parvovirus (U.S.) and areas where there are specific eradication programs. Also, development of expression systems and adjuvents will have significant value in improving the effectiveness and delivery of vaccines.

Table 4.2 shows estimates of the costs of selected diseases, and the estimated markets for vaccines for their control. The biggest animal health problem in terms of cost are foot and mouth disease and mastitis. These problems are estimated to cost $50 billion and $35 billion respectively on a worldwide basis in terms of animal losses, lost production, treatment and eradication programs, and in the case of foot and mouth, barriers to trade in cattle and animal products. However, the foot and mouth market would be largely in the Third World, given the current disease pattern. Mastitis has a significant industry cost in the United States and Europe, although difficulties in addressing this problem through vaccines limit this potential.

There are a range of diseases with smaller industry costs but likely larger or equivalent market size, given the geographic distribution of the product and the ability to address the issue through recombinant vaccines.

Shipping fever, bovine scours and baby pig scours, for example, are very significant disease problems, in particular in a North American context.

On a regional basis, the market for veterinary biotech vaccines in 1992 was estimated as follows (Table 4.3).

Table 4.3 1992 Market Potential for Vaccines and Diagnostics (Constant U.S.$ million)

Region	Vaccines	Diagnostics	Total
U.S.A.	1,606	6,548	8,154
Europe	1,560	7,030	8,590
Japan	571	1,984	2,555
Latin America	1,415	6,610	8,025
Third world	3,600	11,850	15,450
TOTAL	8,752	34,022	42,774

Source: Office of Technology Assessment

Current vaccine research in Canada is focused upon three diseases: shipping fever, viral scours, and infectious bovine rhinotracheitis (IBR). Other diseases are also being studied, but the emphasis is more upon diagnosis. This is perhaps not surprising given the higher market potential for these products. The reason for the higher potential is largely because of:

- multiple use
  - the same animal may use a diagnostic kit more than once
  - several diagnosis may be used before appropriate treatment is discovered
  - when effective diagnosis is achieved, the control used may not be a vaccine.
- value of diagnostic kit approaches cost of vaccine - benefit is that you will know exactly which vaccine to use.

Three disease areas are examined more closely. These are: shipping fever, bovine scours (BVD) and infectious bovine rhinotracheitis. These three disease areas were selected for further evaluation because:

- they are economically important to Canadian livestock producers and to Canadian conditions. All three of these diseases are strongly correlated with stress - intensive confinement operations, handling and shipping, and high grain diets all play a role; these conditions are endemic to the Canadian production system; and

- industry sources say that these are the areas where Canada has a lead-in understanding and developing the technology.

Shipping Fever

Shipping fever is a complex disease that can strike both mature and young cattle at any time of the year. Outbreaks are induced by stress, in the company of both the viral and bacterial vectors. The most common stress vectors are: shipping (hence the name), weaning, fatigue, overcrowding and changing diets.

The disease has particularly strong economic importance in North America due to the amount of stress placed on beef animals by the (relatively) intensive management systems used. Table 4.2 shows that the world wide cost of the condition is approximately $3 billion, and the market potential for an effective product would be $800 million. North American costs of the condition are estimated at $0.5 billion and a market potential of $125 million. Estimates of the world market potential are probably overestimated, as the adoption rates were assumed to be equal in all regions. This assumption would approach reality only if a long enough time span is considered and discounted dollars are used.

The estimate is likely accurate in a North American context, where producers typically expect a cost benefit ratio of about 4:1 for animal health products. Even so it assumes that adoption would approach 100% over time. This is not likely to occur, although adoption rates of over 90% are possible in this case.

Bovine Scours

Bovine scours are a disease caused by viral infection of the gastrointestinal tract and is separate from Bovine Viral Diarrhoea (BVD). The incidence of bovine scours is higher in dairy animals than beef animals, but economic consequences are more likely to be severe in beef herds, where the condition can reach epidemic proportions in a short time. Mortality rates can reach anywhere from 10 to 100% of the calf crop. Outbreaks are strongly correlated with environment and management. Closed, dirty, poorly ventilated housing facilities are most likely to lead to outbreaks.

The North American cost of the condition is estimated at $250 million, and market potential was estimated at $125 million, by the Office of Technology Assessment. This estimate is very optimistic, and assumes that producers will accept a cost/benefit ratio of 2:1, and still adopt 100%. Our estimate is that North American market potential is more in the $50 million range.

Infectious Bovine Rhinotracheitis (IBR)

IBR is a highly infectious disease of the upper respiratory tract, generally occurring in breeding herds of both beef and dairy animals. It is caused by a herpes type virus, and is often accompanied by secondary infections of bacterial pneumonia. The most severe outbreaks occur in beef cow herds, and up to 100% mortality of the calf crop may result. Accurate diagnosis requires laboratory test. The virus can exist without causing any visible signs, and is generally reactivated by stress.

The worldwide cost of the disease is estimated at $2.5 billion, and the cost in North America at $0.3 billion, including the cost of secondary infection. The market potential for products to control IBR is estimated at $75 million, given a 100% adoption rate. This adoption rate is likely optimistic given the latent capabilities of the disease, and the fact that producers may feel that vaccination is not necessary given no visible signs of the disease are present.

4.4 Markets For Immunological Products for Feed Efficiency/Carcass Quality Enhancement

While immunization is most often thought of in terms of disease control, similar procedures can be utilized to modify metabolism. If the proper antigen is supplied, antibodies may be produced to mimic hormones and enzymes necessary to produce desired metabolic changes.

Research and development managers were less certain about the state of the art in these product areas. For example, their comments included the following:

"Not that far - technically possible"

"Lots of hype - biotechnology makes it possible"

"Longer time frame"

"Much to achieve before it can be successful".

Nevertheless, they felt there was significant potential in this area, particularly for "fat reduction", "cholesterol reduction" and appetite modification. It was felt that the current weight and focus on AIDS research would yield significant breakthroughs in this area. At the same time a lot of research was still necessary to understand any cross reactivity with other tissues or organs and the interaction or limitations of current feeding and nutrient utilization to make these products effective.

A significant cloud overhanging the development, introduction and commercial use of these products is the consumer, and to a lesser extent, producer acceptance of these products. Some respondents felt that it may be better to continue to address these issues through breeding within a Canadian context, even though potential improvements can outstrip the rate of improvement through genetic gains.

Following are two examples of the market for immunological agents for use in enhancing feed efficiency and/or carcass quality in dairy cattle and hogs.

Somatostatin Inhibitors

Somatostatin is a hormone produced by the hypothalamus which inhibits somatotropin (growth hormone) release by the pituitary gland. By blocking the production of somatostatin, more growth hormone is released. This technique has applications in both swine and bovine species. Elevated levels of growth hormone have been shown to lead to slight gains in feed efficiency, and significant gains in production in lactating dairy cows. In hogs, an increase (5-10%) in the relative yield of lean meat has been observed, as well as higher birth weights and weaning weights when administered pre-partum to sows.

Dairy cattle: The use of somatostatin in dairy cattle is likely to have similar potential as BST. In the context of BST, gains of 3 - 5 kg per day in increased milk output are possible with some improvements in overall feed efficiency. Within Canada it has been estimated[2] that BST would be used by the equivalent of 40% of all cows for an application period of 180 days. The market potential for this product in Canada would be approximately $50 per cow or $20 million[3], or $200 million in North America and approximately $500-600 million worldwide.

Somatostatin will undoubtedly have different application protocols and adoption profiles. However, the potential may be similar.

Hogs: Benefits of immunizing against somatostatin in hogs occur in two areas. The most easily quantifiable is the increase in carcass index caused by a decrease in backfat. A 10% decrease in backfat would cause an average 4 point increase in index, hence, a 4% increase in market value. This would mean a total benefit in Canada of some 60 million dollars, which suggests that the actual market potential would be $15 million, or about $1.10 per market hog based on a 4:1 payback. The other benefit is the reduction in both mortality and days to market when the product is administered to sows. Heavier piglets tend to withstand the stress of weaning more

[2] Farm Level and Industry Impacts of the Introduction and Adoption of BST in Canada - Canadian Animal Health Institute - 1990.

[3] It assumes that there would be 1 million cows by the time the product has reached full market penetration.

effectively, but insufficient research is available to quantify actual benefits.

Immunization to Reduce Boar Taint

Soon after reaching sexual maturity, male hogs exhibit a characteristic called "boar taint" which renders the meat unfit for consumption. The taint is caused by several testicular hormones which cause the meat to have a particularly unpalatable taste and odour. As a result, male market hogs are castrated well before the onset of puberty. However, intact males tend to gain weight faster, and produce a leaner carcass than castrated males. It is possible to immunize males against the particular hormones which cause the taint, without significantly impairing the production benefits to be derived from the use of intact males. Other benefits include a reduction in aggression, which in some cases would lead to better overall herd health.

If an increase in feed efficiency of 8% is assumed, the benefit to the Canadian industry would be approximately $24 million per year, if all male hogs were administered the product. Depending upon the ease of administration, the actual effectiveness, and any other desirable or undesirable effects, the actual product market potential is estimated at $8 million per year, or slightly more than $1 per hog.

4.5 Markets for Probiotics as Feed Efficiency and Carcass Quality Enhancers

Probiotics are organisms which are introduced to a host organism and have a symbiotic relationship with the host animal. To date most probiotics have been naturally occurring organisms, but work is underway to utilize biotechnology to enhance specific characteristics in the probiotic organism. For example, ruminant animals are dependant upon several organisms (both bacteria and protozoa) for their ability to transform roughage into simpler proteins and sugars. A cow does not digest hay, it digests the fermentation products produced by the organisms in the rumen.

One of the most important applications for probiotics is as an feed additive or enhancer. In any animal's digestive process feed undergoes a number of steps and changes before it can actually be utilized by the animal. The use of probiotics can significantly alter the quantity and quality of the breakdown products. For example, in monogastric animals (such as

swine) fibrous feeds such as alfalfa which could not normally be digested may be converted by micro-organisms into other products which the animal can digest. This conversion may take place prior to feeding through ensiling or fermentation, or it may take place in the animal's gut, if an appropriate probiotic agent is used. The major direct benefit in this case would be the ability to use alternative, and possibly less expensive feeds. Other direct benefits are possible as well. Meat and fat composition of the animal is directly affected by the type of feed consumed. The use of probiotic agents in both monogastric and ruminant animals can lead to more desirable carcass traits, or milk composition.

The challenge is to identify the specific feed components which lead to altered carcass traits, and manufacture an appropriate organism which can survive in the animals gut as well as produce the required components.

Research and development managers are currently skeptical about the role and potential of probiotics in animal agriculture. Their comments include:

"uncertain"
"big question mark"
"not met expectations"
"light years behind - still primitive - hit or miss"
"no proven effectiveness".

The mode of action of probiotic organisms is still not understood. The activity is subject to a wide range of dietary, internal, environmental, and stress related influences which are difficult to isolate even within a research environment. The picture is, at best, "muddled". The consensus among respondents is that until the mode of action or some underlying chemical substitutes are identified as the basis for the productivity, feed efficiency or health status improvements the potential for these products will remain "risk sensitive". Nevertheless, the concept of probiotics is attractive given their passive, environmentally friendly nature, the direction of consumer attitudes toward "natural" products and the current consumer and regulatory environments surrounding the use of sub-therapeutic levels of antibiotics and growth hormones. The use of probiotics in "branded" natural animal products is seen as a significant area of opportunity, particularly within integrated production and marketing systems.

Practical issues that still needed to be addressed in commercializing these products include:

i) ensuring viability of organisms in commercial products

ii) developing mechanisms for protecting the organisms within the feed formulation and feeding process

iii) ensuring that the probiotic organisms can be used with or tolerate existing feed additive products (coccidiostatis, growth promoters, mould inhibitors and therapeutic agents used in the feed or water)

iv) cross registration of probiotics and antibiotics could also be a significant barrier to commercial use, and

v) the relative competitiveness with sub-therapeutic levels of antibiotics.

Current research in Canada in this area is very limited. The focus of activity involves the construction of glucanolytic and hemicellulytic lactobacilli, and the construction of Butyrivibrio fibrisolvens for use as probiotic agents. Additionally, a database of useful organisms is maintained by Agriculture Canada.

Probiotic Market Synopsis

The market for probiotics is not well developed as yet. Only a few of the major feed ingredient or animal health product companies have become involved in this area. Moreover, some who were involved have dropped out (Syntex). The probiotics business is still entrepreneurial in nature with a limited range of products being used or recommended for increased feed efficiency and growth promotion in times of stress or use for treatment of diarrhoea in young animals. The market is still small; estimates of $3 - 5 million in the U.K., $20 - 30 million in the U.S., and less than $1 million in Canada give an indication of current size of this market. Nevertheless it is growing. The versatility, potential use and potential value of the technology will sustain research and development interest in this area.

As with immunological approaches the key uncertainty in this market is how they will be treated from a regulatory perspective.

An example of the market benefits associated with the development of probiotic agents to enable monogastric animals (primarily swine) to digest high quality fibre feeds such as alfalfa as an alternative source of protein has been determined for Canada. The major benefits of such a probiotic would be:

1. an increase in feed cost efficiency of approximately 8%;
2. improvement in health status of the pig herd; and
3. an increased demand for alfalfa.

The major cost to swine producers would be the cost of the product, and the cost of facilities to handle and store an additional feed type, as alfalfa could not completely replace any current feed.

The financial benefits of being able to replace current commercial protein sources for swine is estimated to be some $59 million (see Appendix 4.3). The health status benefits are difficult to quantify but would likely assist in the rate and level of adoption. The health benefits are associated with reducing the incidence of stereotypie and Mastitis, Metritis Agalactia (MMA) in sows. The benefits of a greater use of on-farm alfalfa could also approach $45 million to Canadian hog producers.

Market Size Assessment

While the determination of the market size and likely regional distribution for specific products is difficult to achieve with certainty. We have constructed a spreadsheet model to provide an evaluation mechanism. The analysis is unlikely to be accurate in absolute sense but may be useful in providing assessments of the relative size distribution of market opportunities. This mechanism will be combined with a mechanism for evaluating the attractiveness of specific market opportunities from a strategic perspective in a later section.

The model incorporates:

1. The estimates of either the livestock inventory or number of animals slaughtered for each region;

2. A weighting factor which reflects likely maximum level of usage within a specific region. This weight can be used to reflect the technical, physical and socio-economic features which will affect the adoption of a particular region, based on past experience, an understanding of the product features and benefits, and the prevailing socio-economic conditions and prevailing attitudes in each region; and

3. An estimate of the farm level price for the product in question.

The total world market value of a generic set of vaccines, feed efficiency and product quality enhancement products (Table 4.4) based on the prospective product price parameters at the farmer level of:

		Annual Producer Cost $
i)	Dairy Probiotic	20
ii)	Dairy Quality Enhancement (cf BST)	50
iii)	Cattle Univalent Vaccine (IBR)	5

		Annual Producer Cost $
iv)	Cattle Multivalent Vaccine	10
v)	Cattle Probiotic	20
vi)	Cattle Quality Enhancement	25
vii)	Hog Univalent Scours Vaccine	1
viii)	Hog Probiotic	4
ix)	Hog Quality Enhancement Product	2.5

and series of selected market access weights for each product and region based on previous analysis and assessment.

The market potential for cattle probiotic and quality enhancement products is very significant given the number of cattle, their respective regional distribution and the relative ascribed value of these products, and the market access weightings used. Dairy quality enhancement products have a high market potential.

The distribution of these market potentials given the weightings show the dominance of the North American and Western Europe markets for some of these products (Table 4.5). North American is seen as particularly dominant in cattle vaccine products, quality enhancement products, and hog quality enhancement products. Western Europe has a particularly strong opportunity in the hog and dairy probiotics products market and hog products generally.

TABLE 4.4 BIOTECHNOLOGY MARKET OPPORTUNITY ASSESSMENT EVALUATION FRAMEWORK

	PRODUCT AREA	NORTH AMERICA	WESTERN EUROPE	EASTERN EUROPE	SOUTH AMERICA	REST OF WORLD	TOTAL MARKET POTENTIAL (Gross/Net Value million)
DAIRY(Probiotic)	DAIRY(Probiotic)						
	-Market size						
	(Gross Dollar Value-million)	340	500	1040	570	1950	4400
	-Market access weighting	1.50	3.00	0.50	0.75	0.50	393
DAIRY(Quality Enhancement)	DAIRY(Quality Enhancement)						
	-Market size	850	1250	2600	1425	4875	11000
	-Market access weighting	2.50	1.00	0.25	0.50	0.15	547
CATTLE(IBR/UNIVALENT)	CATTLE(IBR/UNIVALENT)						
	-Market size	245	150	260	155	215	1025
	-Market access weighting	2.50	1.50	0.50	0.75	0.50	119
CATTLE(/MULTIVALENT)	CATTLE(/MULTIVALENT)						
	-Market size	490	300	520	310	430	2050
	-Market access weighting	2.50	1.50	0.50	0.75	0.50	238
CATTLE(Probiotic)	CATTLE(Probiotic)						
	-Market size	2840	1680	3080	3800	8660	20060
	-Market access weighting	1.50	2.50	0.50	0.75	0.30	1545
CATTLE(Quality Enhancement	CATTLE(Quality Enhancement)						
	-Market size	3550	2100	3850	4750	10825	25075
	-Market access weighting	2.50	1.00	0.25	0.50	0.15	1594
HOGS(SCOURS/UNIVALENT	HOGS(SCOURS/UNIVALENT)						
	-Market size	226	348	318	32	672	1596
	-Market access weighting	2.50	1.50	0.50	0.75	0.30	74
HOGS(Probiotic)	HOGS(Probiotic)						
	-Market size	452	696	636	64	1344	3192
	-Market access weighting	2.00	2.50	0.50	0.75	0.30	341
HOGS(Quality Enhancement)	HOGS(Quality Enhancement)						
	-Market size	565	870	795	80	1680	3990
	-Market access weighting	2.50	1.00	0.25	0.50	0.15	139

TABLE 4.5 ESTIMATED DISTRIBUTION OF MARKET POTENTIAL FOR SELECTED ANIMAL BIOTECHNOLOGY

PRODUCT	N. AMERICA	W. EUROPE	E. EUROPE	S. AMERICA	REST OF WORLD	TOTAL
	% of total market					
Dairy Probiotic	13	38	13	11	25	100
Dairy Quality Enhancement (of BST)	39	23	12	13	13	100
Cattle Univalent Vaccine (rBR)	51	19	11	10	9	100
Cattle Multivalent Vaccine	51	19	11	10	9	100
Cattle Probiotic	28	27	10	18	17	100
Cattle Quality Enhancement	56	13	6	15	10	100
Hog Univalent Scours Vaccine	38	35	11	2	14	100
Hog Probiotic	26	51	9	1	12	100
Hog Quality Enhancement Product	51	31	7	1	9	100

5.0 REGULATORY ISSUES

5.1 Product Registration Process

Animal husbandry products manufactured and/or sold in Canada are regulated under two separate government ministries, Agriculture Canada - Veterinary Biologics and Biotechnology Section, and Health and Welfare Canada - Bureau of Veterinary Drugs. The general guidelines to determine which ministry jurisdiction that a particular product would fall into is outlined in a memorandum of Agreement between the two ministries. In general, Agriculture Canada would be responsible for those products that are considered veterinary biologics while Health and Welfare would be responsible for all other veterinary drugs.

5.1.1 Products Registered under Agriculture Canada - Biologics

Agriculture Canada Veterinary Biologics and Biotechnology administers veterinary biologics under the Animal Disease and Protection Act. Under this act, veterinary biologics are defined as:

a) any helminth, protozoa or microorganism
b) any substance or mixture of substances derived from animals, helminths, protozoa or microorganisms
c) any substance of a synthetic origin manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or the symptoms thereof, in animals, or
d) restoring correcting or modifying organic functions of the animal.

Agriculture Canada states that this definition provides the mandate to regulate any product claiming to be a veterinary biologic, produced by modern techniques of biotechnology or by conventional methods.

VBBS has developed a set of guidelines specifically for registration of biotechnology-produced veterinary biologics. These guidelines were designed to harmonize with the registration policies and procedures of our major trading partners, including: the United States, the United Kingdom, Australia, New Zealand and countries within the OECD.

Registration procedures for biotechnology-produced biologics in all the above-named countries are developed on the basis of existing guidelines for conventional biologics. Enhanced environmental safety requirements are the key additional component of biotechnology registration guidelines.

Classification

Under the VBBS biotech guidelines, there are two broad categories of biotech derived veterinary biologics. These categories closely match categories used by the US Department of Agriculture for registration purposes. The categories are:

Class I - includes products prepared for recombinant-derived inactivated organisms such as viruses, bacteria, bacterin-toxoids, virus sub-units or bacterial sub-units, cytokines, monoclonal antibody products used prophylactically, therapeutically or as components of therapeutic kits.

Class II - includes products containing live microorganisms that have been modified and involve introduction of DNA from different organisms or different strains of the same organism; this class consists of product using live vectors to carry recombinant derived one or more foreign genes that code for immunizing antigens and/or immune stimulants.

Principles

Licensing for distribution of a biotech veterinary biologic can be accomplished in four broad stages under Agriculture Canada:

- Laboratory Research and Development
- Controlled Containment Experiments using target and non-target species
- Limited Field Trials using target species
- Licensing of the product

Any product must demonstrate the four qualities of purity, safety, potency and efficacy.

Protocol

Procedures and protocols for registering veterinary biologics follows a General Licensing Requirements model Detailed in Exhibit 5.1. Generally, the Veterinary Biologics and Biotechnology Section considers each registration application on a case-by-case basis. This policy coincides with the policies set out by the OECD Committee for Scientific and Technological Policy.

Class II biotech biologics are often perceived, by the public and to a lesser extent the scientific community, to have a greater environmental risk due to the adding or deletion of genes and the live nature of the biologic. Extra precaution is advised to firms seeking to licence biotech biologics by VBBS to ensure that addition or deletion of specific genetic information to the virus or bacteria vector does not impart increased virulence, pathogenicity, or survival advantages that is greater than the natural form of the organism. However, VBBS recognizes that deletion of some organism functions can also reduce risks of pathogenicity of biological agents. This advised precaution is addressed in enhanced environmental assessment guidelines that apply to all biotech biologics an particularly to Class II biologics.

Safety guidelines and protocols for laboratory research follow the Medical Research Council and Laboratory Centre for Disease Control (MRC/LCDC) Laboratory Biosafety Guidelines. Other protocols are proposed in the "Product outline" submitted to VBBS at the initial stages of the licensing process. Negotiation on protocols are possible at the initial stage and at the evaluation stage subject to requirements of an Ad Hoc Committee to review the specific application.

Exhibit 5.1

STEP	REQUIREMENTS	SPECIFIC TESTS
1.	Preparation and certification of master seed (bacterial or viral) stocks	For R-DNA Master Seeds - construction map of bacterial plasmid Follow MRC/LCDC 1989 Lab Biosafety Guidelines
2.	Manufacture of experimental product to minimum outline specifications	Product Outline Specifications: 1) description of process of preparation of vet biologic 2) methods of handling, storing, administering, and testing 3) tests use to establish purity, safety, potency and efficacy.
3.	Host animal efficacy (immunization and challenge)	Controlled Containment Experiments - Follow MRC Lab Safety Guidelines or negotiate conditions with Ag. Canada Veterinary Biologics & Biotech Section (VBBS)
4.	Development of potency test for serial release	Controlled containment Experiments - Negotiate conditions with VBBS
5.	Preparation of three consistency serials	Each serial release will be tested for purity, safety and efficacy. Specific procedures negotiable with VBBS.
6.	Field safety tests	Includes human, animal and environmental safety assessment - VBBS negotiated conditions for trial methodology, Environmental Assessment requirements modelled on USDA requirements (Appendix 1)
7.	Satisfactory completion of all test requirements in Outline of Production	Ensure consistency and recovery of specific antigenic material - Must ensure removal of excessive antibiotic levels and bacterial endotoxins. Specific test procedures negotiable. Negotiations subject to evaluation on case-by-case basis by Ad-Hoc Committee
8.	Submission of samples to Vet Biologics Evaluation Lab for confirmatory testing	
9.	Acceptance of labels	
10.	Licensing	
11.	Release of prelicensing serials	

5.1.2 Products Registered under Health and Welfare - Probiotics

Health and Welfare Bureau of Veterinary Drugs (BVD) is in the process of developing biotechnology veterinary drug guidelines and revising guidelines for conventional drugs. The legislation that BVD regulates drug registration under is the Food And Drug Act and the Food and Drugs Regulations.

Classification

The Food and Drug Act defines a drug as any substance or mixture of substances manufactured, sold or represented for use in:

a) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state or the symptoms thereof, in man or animal;

b) restoring, correcting or modifying organic functions of man or animal; or

c) disinfections in premises in which food is manufactured, prepared or kept.

It is our understanding that under the memorandum of agreement between Ag. Canada and Health and Welfare Canada, that BVD administers registration for all biotech animal health product other than injectable biologic vaccines. Probiotics and hormones (ie. the end product not the microbiological vector) produced by biotech methods would be under the auspices of BVD. However, no specific guidelines exist as yet for products produced by biotech methods.

Probiotics pose a unique problem for classification. As a feed additive, it would depend on the claim made by the firm seeking a licence whether it was classified as a drug or a nutritional additive, in which case it would be administered under the Agricultural Feeds Act by the Feeds and Fertilizers Division of Agriculture Canada. If the probiotic additive claimed to "modify organic functions" , for example, significantly increase feed efficiency, the additive would be considered a drug. In practice, there is some degree of subjectivity in the classification of the additive, whether probiotic or conventional.

Protocol

The BVD provides a very detailed and specific guide for preparation of veterinary new drug submissions. A new drug is defined under the Food and Drugs Act as a drug that:

a) contains or consists of a substance, whether as an active or inactive ingredient, carrier, coating excipient, menstruum, or other component;

b) is a combination of two or more drugs with or without other ingredients;

c) the manufacturer prescribes, recommends, proposes or claims a use as a drug or as a condition of use as a drug, including dosage, route of administration, or duration of action;

that have not been sold as a drug in Canada for sufficient time and in sufficient quantity to establish in Canada the safety and effectiveness of that substance for use as a drug.

A new drug goes through three phases under the BVD system before being licensed for sale or manufacture for general distribution, the phases include:

- Experimental Studies
- Investigational New Drug Submission
- New Drug Submission

Detailed reports and certification is required for each of these stages. To illustrate, the following chart details the specific requirements outlined in the BVD Guide for Preparation of Veterinary New Drug Submission.

New Drug Submission Reports Required	Stage Research Conducted Under
1.Manufacturing and Quality Control	Completed prior to New Drug Submission
2.Laboratory Animal Toxicity Studies 3.Pharmacology and Residue Studies	Experimental Studies Certificate
4.Intended Species Safety 5.Efficacy Studies 6.Medicated Premix Efficacy Studies - Medicated Premixes for Growth Promotion or Increased Feed Efficiency - Medicated Premixes for Concurrent Use - Medicated Premixes Containing Drugs in Fixed Combination	Investigational New Drug Studies

Each of these specific reports consists of both comprehensive study reports and sectional reports. BVD details specific test for sectional reports. To illustrate the level of detail required by the BVD in each of the required studies, the following table lists the specific tests required within the Laboratory Animal Toxicity Studies:

1. Acute Toxicity Studies
    - 1.1 Acute Oral Toxicity
    - 1.2 Dermal Sensitization
    - 1.3 Acute Dermal Toxicity
    - 1.4 Primary Skin Irritation
    - 1.5 Primary Ocular Irritation

2. Subchronic Oral Toxicity Studies

3. Chronic Toxicity Studies

4. Carcinogenicity Studies

5. Reproductive Studies

6. Teratogenicity Studies

7. Mutagenicity Studies

For certain specific tests, BVD provides a description of the level of statistical significance required to meet the level of safety or efficacy necessary for the drug to achieve registration. Upon completion of all the requirements under the Food and Drug Regulations a Notice of Compliance is issued to the applicant with a Drug Identification Number (DIN).

5.1.3 Potential Impacts of Registration Guidelines

The product registration guidelines for biotechnology products have an number of associated potential impacts.

Firstly, due to the ad hoc nature of the VBBS registration guidelines, the potential exists for using the process as a socio-economic policy instrument. That is, the VBBS approach is subject to discretion which may make it very easy or very difficult for specific products to become licensed. This potential exists in other countries and actually occurs in practice in certain European countries, according to industry sources.

Secondly, though written definitions and agreements between BVD and VBBS exist, there is still considerable potential for interpretation as to which jurisdiction a particular product falls into. Furthermore, as political and bureaucratic personnel change this potential for interpretation increases.

Thirdly, industry perception is that the BVD guidelines may be too restrictive and not appropriate for animal health products. The BVD has developed complete and structured requirements for human drugs without enough consideration for production and economics concerns of the animal husbandry industry. Generally, however, the BVD guidelines are seen as tough, fair and having a strong scientific basis.

5.2 Patent Process

5.2.1 Patent Eligibility

Background

The grant of a patent provides an inventor with exclusive right, privilege and liberty of making, constructing, using and vending of a patented product. Patented medicines, however, may be produced or prepared by a person other than the patent holder through a compulsory licence. The compulsory licence gives another person on the right to produce the medicine and establishes the royalty rate paid to the patent owner. In effect it provides a generic firm the right to demand the formula of the medicine from the patent owner and produce in direct competition.

Patent legislation in Canada that directly affects the manufacture and sale of biotechnology animal husbandry products is included in section 39 of the Patent Act. The act, Bill C-22, was revised to address biotechnology in Fall of 1987. A specific clause was included for medicines produced through microbiological processes, related to naturally occurring substances. This clause is in effect for four years (to November 1991) and links any specific patent claims on a resulting food or medicine to the process used to produce it. Thus, a manufacturer using a different process to manufacture the same product does not violate the previous patent. When the four years are over, the claims will be directly on the product and not the process. In 1991, the product itself will be protected under patent claims.

Bill C-22 established an length of time during which a holder of a Canadian patent can be assured the exclusive right to sell that medicine in Canada (the period of exclusivity). In exchange for this assurance, the Canadian pharmaceutical industry voluntarily undertook the goal of doubling its ratio of research and development expenditures to sales in Canada by the end of 1996.

Classification

Patent legislation covering animal husbandry products uses definitions different from

licensing definitions under both VBBS and BVD. A patentable animal husbandry product is a medicine, which specifically is:

> Any substance, or mixture of substances, made by any means, whether produced biologically, chemically or otherwise, which is applied or administered *in vivo* in any manner to aide in the diagnosis, treatment, mitigation or prevention of diseases, symptoms, disorders, abnormal physical states, or to modify organic functions in humans or animals (includes vaccines, topical preparations, anaesthetics and diagnostic products used *in vivo*).

Effective Protection

A patent generally provides ten years of exclusive right to produce a medicine. The period of exclusivity for veterinary medicines that are naturally-occurring and produced by microbiological means, is 10 years from date of filing for patent. The patent and the right to exclusive production are granted after filing.

Potential Impacts of Patent Legislation

There are a number of issues and/or controversies surrounding the patent of biotechnology-produced medicines. In particular, some controversy over the eligibility of live entities for patent exists, since the live entity is naturally occurring rather than invented regardless of the process used to produce them. Since live vehicle vaccines are a significant biotech product in the context of this study, the issue of patenting live entities is very important. That is, live vehicle vaccines may not be protected under patent legislation at all.

Another important issue is how patents are applied to the processes of biotechnology versus the products of biotechnology. That is, given that the entities themselves may not be patentable and that the processes to produce certain biotech products are extremely complex and often unique, a patent on these process may be effective in providing some financial protection and benefit to firms doing biotech research. In contrast, simpler biotech products such as chemicals and hormones, may be easily duplicated by other processes yet have complex chemical structures that are more easily patentable. For these products, patent on the product may be most effective protection for the researching firm. Thus, there is some

degree of conflict in how patents should be generally applied with respect to biotech products.

5.2.2 Patent Medicine Price Review Board

Under Bill C-22, provision was made for the establishment of a Patent Medicine Price Review Board (PMPRB). The mission of the board is to monitor and review patent medicine prices in order to ensure that these prices are not excessive and to report on the price trends of medicines and on the research and development expenditures in relation to sales revenues of patentee firms and the industry in general.

The Board has adopted an approach to communicate to patent holders and applicants a compliance process and price guidelines that will assist the industry , the public and the Board itself in understanding what prices the Board might consider to be excessive and would encourage patentees to comply with the Board's guidelines voluntarily.

Classification

The Board uses the definition of medicine as set out in Bill C-22 (detailed as above), but further classifies new medicine into three categories. New drugs (medicines) are identified by a new Drug Identification Number (DIN) issued by Health and Welfare upon completion of the requirements described in Section and issuance of a Notice of Compliance (NOC) and each new drug (medicine) applying for patent with a new DIN are grouped as follows:

1. Existing Dosage Form of an Existing Medicine

2. New Dosage Form or New Chemical Entity - Breakthrough or Substantial Improvement

3. New Dosage Form or New Chemical Entity - Other New Medicine

Pricing Evaluation Procedures and Principles

Each category has a corresponding set of methods to analyse whether a price is excessive, detailed as follows:

Category	Principle
1.	a) The price of the new DIN should bear a reasonable relationship to the price per kilogram of other DINs of the same medicine in the same or comparable dosage forms sold by the same patentee;
	b) Where the above is not appropriate, the Board may determine whether a reasonable relationship exists based upon a comparison of pricing relationships of other DINs in the same therapeutic class having the same or comparable dosage forms;
	c) Where the above is not appropriate, the board will conduct a comparison of pricing relationships among DINs of other medicines in other therapeutic classes having the same or comparable dosage forms;
	d) Where the above are not appropriate, the Board may conduct a therapeutic class comparison (The process for Therapeutic Class Comparison is detailed in Exhibit 5.3);
2.	The price of a breakthrough medicine should not exceed the prices of all medicines in the same therapeutic class and the median international price. Where it is not possible to conduct a therapeutic class comparison, the board will primarily consider the median international price in determining whether the price of a new breakthrough DIN is excessive;
3.	The price of new dosage forms of existing medicines or new chemical entities should not exceed the prices of all medicines in the same therapeutic class (in accordance with therapeutic class comparisons methodology detailed in Exhibit 5.3).

Requirements for Expenditure of Revenues on Research and Development

The PMPRB has no legislated power to enforce compliance of patent holders to a certain level of expenditure on research and development in relation to sales revenue. However, patent holders are required to report relevant data to the board for calculation of R&D to sales ratios

for publication. Public commitment of the member firms of the Pharmaceutical Manufacturers Association of Canada (PMAC) appears to be driving the increase in research and development as percentage of sales rather than legislated increases, according to the 1989 *Annual Report of the PMPRB.*

Potential Impact of PMPRB on New Drug Introductions

An number of important issues arise from the analysis of the effect of the PMPRB on the animal health and husbandry product industry.

First, due to the price restrictions on new products, there is the potential for firms opting not to sell products in Canada since they know in advance that they cannot gain the return on investment they need given the existing prices for products in the same therapeutic class in Canada.

Second, since the size of the market in Canada for animal health medicines and medicines in general is relatively small compared to other countries (eg. US and EEC) the sales of individual firms are thus also small. The proportionate research and development expenditures suggested and voluntarily complied with are also small and perhaps inefficient.

5.3 Summary of Regulatory Issues and Implications

The market and strategic opportunities for Canadian biotechnology-based animal husbandry products is affected by government regulations mainly through product registration regulations and process and patent legislation and process. Biotechnology animal husbandry products will fall under two separate sets of registration guidelines depending upon the nature of the product. Patent legislation and patent medicine pricing regulations will affect biotechnology-based animal husbandry products will affect only those products which apply for patent. The following table summarizes some of the specific issues and the corresponding implications affecting strategic and competitive opportunities for biotech animal husbandry.

Exhibit 5.3

Issue	Implications
Ag Canada VBBS Registration process is mainly Ad Hoc	Guidelines open to discretion and use as socio-economic device - potentially, products can be either easily passed or find it very difficult to pass - firms may incur increased time and expense depending on ad hoc testing requirements
Restrictions on patent of live vaccine products	Creates economic disincentive to invest in biotechnology research because duplication of product is very easy and thus entrance into market is also very easy
Price restrictions under Patent Medicine Price Review Board	Given high initial research costs for biotech, price restrictions may prevent earning of adequate returns to research and risk
Food and Drug Act not oriented to veterinary drugs	Production orientation of animal husbandry products not recognised - a product may demonstrate marginal increases in efficacy but do so at greatly reduced costs thus making large economic gains.
Different Acts for product registration, definitions of biotech products,	Similar products potentially given different assessments and unequal treatments As well, some products may fall through both sets of regulations

6.0 THE CANADIAN ANIMAL HEALTH & BIOTECHNOLOGY ENVIRONMENT

This chapter describes the competitive animal health and biotechnology environment within Canada. Manufacturers of vaccines, and growth promotants are listed, as well as areas of particular strength or existing proprietary products. The resources available in Canada are described as well as the window of opportunity for the major products discussed in this report. The chapter ends with an overview of the strengths, weaknesses, opportunities and threats facing the industry.

6.1 Domestic Activity and Profile in Vaccines

Vaccines may be developed using several different conventional or biotechnological processes. At the present time, their are a large number of conventional vaccines in development, and on the market, while there are relatively few biotech vaccines available. This section examines the competitive aspects of vaccine development in Canada by providing an assessment of biotech firms and activity in this area, as well as an overview of activity in the area of conventional vaccine development. In overall terms, Canada is "right up there" with respect to a perceived capability for development of biotechnology derived vaccines. This perception was strongly associated with VIDO/Biostar and Langford Laboratories/University of Guelph.

Biotech Vaccine Sector

Biotech vaccines may be divided into two types. The first are recombinant vaccines, which are developed when the molecule (sub-unit) necessary to elicit an immune response is extracted from the pathogenic organism and transferred to a benign organism which can act as a carrier. This type is that most commonly developed through biotechnology. The second type are called peptide vaccines. These are developed by joining peptides in specific sequences to copy the antigenic sites on certain viruses.

TABLE 6.1 Domestic Companies Involved in Biotech Vaccines

COMPANY/ ORGANIZATION	AREA OF ACTIVITY		
	DISEASE NAME	TARGET ORGANISM	COMMERCIAL PRODUCT (Brand Name)
Biostar/Vido	Shipping Fever (Bovine) Pneumonia (Bovine) Infectious Bovine Rhinotracheitis (IBR) Bovine Viral Diarrhea (BVD) Pneumonia (Swine) Calf Scours	Pasteurella haemolytica Haemophilus somnus Bovine Herpes virus Pestivirus Spp. Actinobacillus pleuropneumoniae Rotovirus, coronovirus, E. Coli	Ecolan
Industrial Biotech Centre/OVC	Pneumonia (Swine) ? others not disclosed	Actinobacillus pleuropneumoniae	
Langford/Cyanamid	Shipping Fever ? others not disclosed	Pasteurella haemolytica	Presponse *
Institute Armand Frappier	Parvovirus (Swine) Haemophilus pneumonia (Swine) Infectious Bovine Rhinotracheitis	Parvovirus spp. Actinobacillus pleuropneumoniae Bovine Herpes Virus	
Vetrepharm Inc.	Upper Respiratory Diseases (Equine) ? others not disclosed	Equine Herpes virus Influenza A Equine 1 Influenza A Equine 2	Equimine **
Smith Kline & French	Not disclosed		
Salsbury	Neonatal diarrhea (Swine)	E. Coli	Ecobac-Plus

* Developed by OVC, licensed to Langford
** Immunostimulant -- not a true vaccine

The majority of vaccine research in Canada is occurring with sub-unit vaccines. Two public institutions, The National Research Council (NRC), and Agriculture Canada's Research Branch play a major role in the development of animal vaccines. The NRC is a major source of funding to both Agriculture Canada and private and semi-private institutions. Agriculture Canada provides some funding and substantial personnel and infrastructure through its research stations to the cause of vaccine development.

Private and semi-private organizations who are involved in the development of biotech vaccines are shown in Table 6.1. The specific diseases are listed where known, and products which have been brought to market are identified. It is evident that there is some competition in developing vaccines for shipping fever, infectious bovine rhinotracheitis (IBR) and haemophilus pneumonia. In general, it can be said that there is more cooperation than competition in this area, since information on techniques are generally published, and available to all researchers, and because of the importance of the NRC and Agriculture Canada. Four companies/organizations where identified who are doing research into sub-unit vaccines, and who would not identify the full extent of their activities.

Conventional Vaccine Sector

Conventional products consist of live and killed vaccines.

Live vaccines consist of living organisms which replicate in the recipient animal. One form of live vaccine consists of an attenuated strain of a disease producing organism. An example would be lungworm vaccines for cattle, which are produced from the virulent organism, but are irradiated so that the organism cannot complete its life cycle. A second type of live vaccine consists of a species of organism closely related to the disease producing organism. This species is able to stimulate an immune response which is also effective against the disease causing organism. A classic example of this is the original smallpox vaccine developed using the organism responsible for cowpox.

Killed vaccines are either purified, inactivated and concentrated preparations of the disease causing organisms, or purified preparations of bacterial toxins.

Conventional live vaccines produce a stronger and longer lasting immunity, but are susceptible to unintentional deactivation, or may become contaminated with other pathogens during

preparation. Killed vaccines are more stable, but do not elicit the complete range of host immune responses, and are thus less effective.

A number of conventional vaccines are available for most of the diseases for which biotech vaccines are under development. These products are listed in Tables 6.2a bovine vaccines; Table 6.2b, swine vaccines; and Table 6.2c, equine vaccines. All of these products are available in most international markets as well, and would provide varying degrees of competition, based upon their efficacy and cost, to any new biotech derived vaccines.

TABLE 6.2a BOVINE BIOLOGICALS
(currently available)

DISEASES	COMMERCIAL PRODUCTS	MANUFACTURER
IBR	Bovilan RP Bovishield IBR-$P1_3$ 3 4 IBR-$P1_3$-BRSV Cattlemaster 3, 4 IBR-$P1_3$ IBR-$P1_3$-BRSV	Langford Inc. Norden Laboratories Norden Laboratories
BVD	Cattlemaster BVD-K, 4 Bovishield 3 Horizon Sentry Triangle	Norden Diamond Scientific Boehinger Ingelheim Ayerst
CALF SCOURS	Scour Guard Calf Guard	Norden
PNEUMONIA	Sentry-Somnugen Somnugen	Boehringer Ingelheim

TABLE 6.2b PORCINE BIOLOGICALS
(currently available)

DISEASES	COMMERCIAL PRODUCTS	MANUFACTURER
Parvo virus	Parvo-Erycheck	Vetrepharm
	Parvopro	Salsbury
	Parvo Vac	Norden
	Parvocheck	Vetrepharm
	Parvopig	Langford
	Suvoxyn	Solvay
	Farrowsure	Norden
	Farrowcheck	Vetrepharm
	Sowvac	Langford
Haemophilus Pneumonia	Pleuroguard	Norden
	Pleurovac	PVU
	Pneu-Pac	Shering
	Suvaxyn HPP	Solvay
	Concord	Diamond Scientific

TABLE 6.2c. EQUINE BIOLOGICALS
(currently available)

DISEASES	COMMERCIAL PRODUCTS	MANUFACTURER
Equine Influenza, 1 and 2	Equi-Flu	Coopers
	Equicine II	Haver
	Flumune	Norden
	Fluvac	Ayerst
	Inflogen	MTC
	RhinoFlu	Norden
	Trouble E	MTC
	Encevac	Haver

6.2 Domestic Competitiveness in Feed Efficiency and Carcass Quality Enhancement

In meat animals there are two separate aspects to carcass quality. First, there is the proportion of usable or high value components of the animals carcass, for example, improving the overall yield of lean meat. Second is the actual composition of the tissue itself, for example, the lipid structure of the fatty tissue. In meat animals there is often a link between the first type of carcass quality and feed efficiency, since more efficient animals tend to produce a leaner carcass.

In dairy, the issues are similar. Quality may relate to the relative proportions of the major components, or it may relate to the specific make-up individual components.

There are numerous mechanisms by which both carcass quality and feed efficiency improvements may be approached. These are described in Figure 6.1. In Canada, virtually all potential mechanisms are represented by one or another research institution or company. Those companies who are utilizing biotechnology in their approach are detailed in Table 6.3.

Figure 6.1 Approaches to Improved Feed Efficiency/Carcass Quality

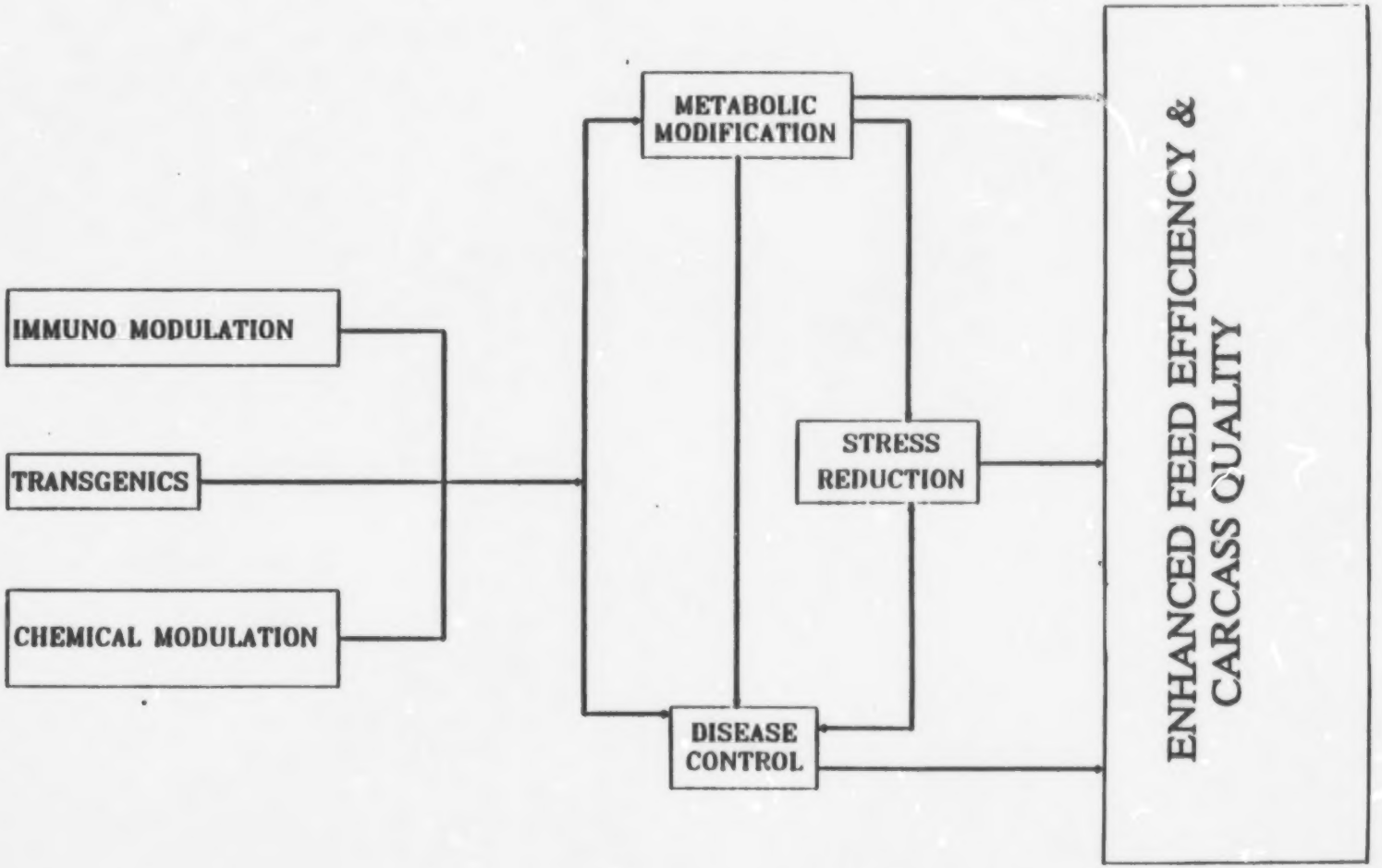


Table 6.3 Companies Using Biotechnology to Develop/Produce Products for Feed Efficiency/Carcass Quality

Approach Used	Company/Organization
Immunization Techniques	Agriculture Canada
	Industrial Biotech Centre/OVC
	Biostar/VIDO
Other Animal Health (primarily antibiotics by fermentation)	Eli Lilly
	Merck Frosst
	Novopharm
	Pfizer canada
	Rhone Poulenc
	Upjohn Animal Health
Genetics (primarily embryo transfer techniques)	Alta Genetics Inc.
	B.C. Artificial Insemination Centre
	Bova Tech Livestock Ltd.
	Centre D'Insemination Artificielle Du Quebec
	Semex Ltd.
	Western Breeders International.
Hormonal Products	Agriculture Canada
	Biostar/VIDO
	Cyanamid
	Eli Lilly
	Industrial Biotech Centre/OVC
	Monsanto
	Upjohn
Feed Products (amino acids)	Bio-Feed Ltd.

Because of the numerous techniques/mechanisms for improving carcass quality and feed efficiency, the competitive environment takes on considerable complexity. This is compounded by the fact that, to some extent, various techniques/mechanisms used together may be either neutral, additive, synergistic or mutually incompatible.

Conventional methods for improving feed efficiency fall into four categories:

- improved management/environment;
- conventional breeding for desired traits;
- use of low levels of antibiotics;
- use of hormone implants (beef only).

Depending upon the type of biotech approach in question, any of these four conventional approaches may assume some competitive importance. There are currently numerous products registered for growth promotion/feed efficiency for both bovine and swine species (see Table 6.4).

6.3 Resource Inputs/Capability

The main infrastructure/resource requirements in producing biotechnology products for animal care are intellectual in nature. Canada's capability in terms of intellectual resources is rated highly, both in terms of the number of professionals working in this area, and in terms of the supporting educational infrastructure/institutions to develop this expertise. The investment in hardware in significant as well, particularly as the research begins to be applied and scaled up. In this area Canada is somewhat behind other larger countries, because funding for such investment, either in terms of government assistance, or cash flow generated from sales of products, has been limited.

Currently, there are slightly less than 100 Ph.d level researchers in Canada active in biotechnical research aimed at animal husbandry/health issues. Almost three quarters of these are employed in public and semi-public organizations such as Agriculture Canada, the universities and veterinary colleges, and organizations such as VIDO (Veterinary Infectious Disease Organization). The balance are employed by large and small private sector corporations such as Semex, Vetrepharm, Eli Lilly, and Langford (division of Cyanamid).

The single most important source of funding for these activities is through the National Research Council (NRC). For the 1988/89 fiscal year the NRC funded some 55 person years (PY's) of professional (Ph.D level) research, as well as 54 PY's of technical support through direct grants. The Federal Government also has major input through Agriculture Canada (particularly the Research Stations), and various Economic and Regional Development Grants (ERDA's).

In terms of hardware, Canada's major limitation is in terms of the ability to scale up to commercial production. Limited facilities exist to provide commercial quantities of products, or sufficient quantities to use for clinical testing in support of registration. Both VIDO and The University of Guelph (Guelph Waterloo Biotech) have limited pilot scale facilities.

6.4 Window of Opportunity/Sustainable Advantage

The window of opportunity for products discussed in this report is difficult to quantify in absolute terms, nonetheless, it is possible to make a qualitative assessment of the relative opportunity.

The window of opportunity for individual products refers to the time between the identification of a market need, and the fulfilment of that need by an alternative product. It depends upon the interaction between:

1. the development time required to produce the product;

2. the regulation requirements for the product as well as for competitive products under development; and

3. any concurrent changes in the market environment which may enhance or detract from the need for a product, or which may effect the relative value of competing products or technologies.

The sustainable advantage of a product refers to the length of time for which a product can maintain a market advantage over products and techniques which fulfil a similar market need. It refers to the ability achieve and maintain competitive advantage. A number of factors

influence the competitive advantage of a product including:

1. proprietary intellectual knowledge;

2. patents;

3. tariff and non-tariff barriers;

4. the cost effectiveness/efficacy of the product;

5. the degree to which the benefits of the product are additive to new competing/alternative products or techniques; and

6. the attitude of the consumer towards innovation, and there willingness to try competitive products/processes.

If we examine the types of products described in this report we see that certain classes of products lend themselves to a higher degree of sustainability.

Vaccines for Animal Health

The window of opportunity for most of the vaccines discussed in this document is relatively short, (1-5 years) due to the immense amount of competition in this area. Multivalent vaccines have a somewhat longer window of opportunity, due to the technical difficulties which are faced in there development. the sustainability of these products relate directly to the degree to which patent protection can be applied, and to the degree of cost effectiveness which can be achieved relative to alternatives. In this sense, univalent vaccines rate low, while the proprietary technical knowledge involved in producing multivalent vaccines gives them medium sustainability.

Vaccines for Animal Production

Due to the comparative lack of competitive research in this area, the window of opportunity for products utilizing immunological approaches to improving animal production is somewhat longer than that for animal health vaccines. The sustainable advantage should also be

somewhat longer due to the increased opportunity for proprietary knowledge to act as a barrier to new market entrants.

Probiotics

The window of opportunity for probiotic products is likely to be comparatively long because in this market place there are almost infinite degree of efficacy, and no "perfect" product. This is compared to the vaccine market where there is a more logical end point.

On the other hand, the sustainability for most probiotic products may be somewhat limited by the relative lack of effective patent protection, and the speed by which new products may be made obsolete due to changes in the environment. For example, a probiotic product may be compatible with existing antibiotics used for health management, but newer products may be detrimental to the probiotic as well as the target organisms.

TABLE 6.4 PRODUCTS CLAIMING GROWTH PROMOTION AND ENHANCED FEED EFFICIENCY

PRODUCT	MANUFACTURER	ANIMAL	
INFEED ADDITIVES AND MEDICATIONS			
Aureo S 700	Cyanamid	Beef Cattle	Antibiotic/Antibacterial
Aureo Sp 250	Cyanimid	Swine	Antibiotic/Antibacterial
Aureomix 625	Cyanimid	Swine	Antibiotic/Antibacterial
Aureomycin	Cyanamid	Poultry	Antibiotic/Antibacterial
Lincomix 44	Upjohn	Poultry	Antibacterial
MGA 100	Upjohn	Beef (Heifers)	Hormone
Neo-Terramycin 50/50	Pfizer	Beef	Antibiotic
Pen G. Strep	BioAgri Mix	Poultry	Antibacterial
Pen P. Strep	APA	Poultry	Antibacterial
Stafac 22, 44	Smith Kline	Poultry, Swine	Antibiotic
Terramycin 10 Premix	Pfizer	Poultry, Swine	Antibiotic
Tylan 10, 40	Elanco	Swine	Antibiotic

TABLE 6.4 (cont.) PRODUCTS CLAIMING GROWTH PROMOTION AND ENHANCED FEED EFFICIENCY			
PRODUCT	MANUFACTURER	ANIMAL	
Chlorachel 250	Pfizer	Swine	Antibacterial
Super Chlorachel 250	Pfizer	Swine	Antibacterial
Super Chlor 250	BioAgri Mix	Swine	Antibacterial
3-Nitro	Salsbury	Swine/Turkeys	Antibacterial
3-Nitro 4-Hydroxylphenyl-Arsenic Acid	Rhone-Poulenc	Swine/Poultry	Antibacterial
Rumensin	Elanco	Beef	Cocudiostat
IMPLANTS			
Steer-oid/Heifer-oid	Boehringer Ingelheim	Beef	Hormone
RalGro	Pitman-Moore	Beef	Hormone
Synorex	Syntex	Beef	Hormone
Compudose	Elanco	Beef	Hormone

6.5 Strengths and Weaknesses of Animal Biotechnology Environment

The Canadian biotechnology environment encompasses a number of features which research and development managers saw as potential advantages and disadvantages of the Canadian biotechnology environment.

The strongest perception was that Canada had a high level of expertise and capability in the critical area scientific and basic research area. While relatively small in quantity, it was regarded as being of high calibre, well trained and committed.

"Scientists/expertise - good universities/good contacts"

"Expertise - universities/government

"Expertise - a lot in Canada"

"Well trained scientists"

"Broad education/good training"

"Highly committed".

Two of the senior research and development managers indicated that Canadian-based scientists typically had a broader understanding of research and development, and animal production issues relative to their U.S. counterparts. Both attributed part of this to better secondary education.

While this resource base has strength, it is perceived as being vulnerable to the U.S. presence and pocketbook. However, this capability was seen to be augmented by government supported research facilities for collaborative research and product testing. Some of the managers were supportive of the investment, "sticks and carrots" provided by available investment incentives, matching research funds, the Canadian tax system and Bill C-22. In this latter regard, the necessity to do research in Canada provided opportune time to consider

serious investment in R&D if the environment was right for the specific research activities.

The scientifically oriented and the relatively consistent set registration protocols vis a vis the U.S. provided a positive product development environment. Similarly, the health status of Canadian livestock provided a reassuring environment for vaccine development. At the same time, it provides a significant barrier to work on those areas where it is free of a particular disease; e.g., foot and mouth, pseudo-rabies, etc.

Another positive feature of the Canadian biotech research and product development environment is that the Canadian consumer producer and society attitudes are less negative to this area of activity than in other jurisdictions, particularly Europe. In this jurisdiction, potential markets were subject to strong consumer and regulatory responses and barriers to specific product areas, particularly in the growth promotion area. Additionally, research and development facilities were often "armed camps" (in Germany and the U.K., particularly), a response to strident militaristic attacks on such institutions by animal welfare groups. Hence, an uninviting research environment.

A potential commercial weakness for Canadian based companies is a lack of presence in the United States. That is, it was perceived that "as with any other country", it was easier to get there (products registered) from there (business operators in the United States). This feature would also be important from the perspective of developing or providing a commercial capability for marketing licensed products in the North American market.

6.6 Opportunities and Threats

Perceived opportunity areas in biotechnology research and development covered most of the areas under consideration in this analysis. That is,

i) multivalent vaccines for shipping fever, the respiratory disease complex, and mastitis;

ii) carcass quality improvement through genetic and immunological approaches with specific focus on fatty acid reduction and cholesterol; and

iii) new growth and feed efficiency enhancement products which do not negatively affect the human condition.

One area that is not under consideration was Agriculture Canada, who was seen to have a lead in this area relative to the United States (was the aquaculture biotechnology research activity in Nova Scotia and British Columbia).

Animal biotechnology was not seen to be the "be-all and end-all" of animal agriculture. There was still significant opportunities in conventional research and development livestock production activities, notably in developing effective delivery systems for existing technology to extensively managed livestock (e.g., range cattle).

Development of a strong research and development base in the veterinary sector could be used as a springboard to development of a base in the human biotechnology product field, either directly or indirectly through use of product analogues. The human biotechnology field was perceived to have higher market potential and perhaps lower risks. Some respondents felt that animal biotechnology firms/organizations may need this connection or capability to sustain the veterinary research and development activity. At the same time, there was always the threat of becoming too fragmented. Biostar, for example, was considered to be "spread too thin" (cloning Lorne Babiuk was suggested as one approach to solving this problem).

A key opportunity was seen to be packaging the positive overall biotechnology research and development environment together, viz:

- the base of expertise
- the research and regulatory environments
- access to the U.S. market
- similarity of U.S./Canadian production systems
- the university and government resource base,

and market this capability to non-North American companies/organizations. A potential weakness of this current package was the limited commercial production base and support mechanisms for commercial business development. A more subtle threat to this development was a perception as to "whether Canada has the drive or will to do it"; "VIDO/Biostar were seen as world-class but needs people funding"; similarly, "Langford has limited budgets"; and

the generic "Low capitalization/limited resources/fragmentization and limited product lines" were the real barriers to development of any capital intensive and high risk venture.

Other threats, too, were identified, including:

- difficulties in effectively patenting vaccines, particularly univalent vaccines;
- rationalization of research, development and marketing activities among North American animal health companies resulting from free trade and other commercial forces; and
- a potentially volatile and changing socio-economic environment.

Non-development of any biotechnical based animal products was not seen as a great threat to Canada or Canadian agriculture since most technology developed for the world market is accessible. The only significant threat to non-development would be to lose some of the gains, leadership and resources in the biotechnology vaccines sector itself. This is perhaps most critical in the vaccines area where the window of opportunity is shorter. Non-participation in the probiotics area has the lowest risk, given the current state of the art and a perceived ability to pick up the technology if this approach becomes more certain and risk-free.

7.0 THE INTERNATIONAL COMPETITIVE ENVIRONMENT

This chapter examines the degree of competition with other nations in terms of the number of countries involved in developing products/processes for animal husbandry.

All major western countries are involved to some degree in the pharmaceutical (vaccine) area (see Table 7.1). To what degree these countries are targeting animal vaccines is not specified. The area of "agriculturals", including reproductive techniques, hormones and feed enhancers is somewhat less targeted. The U.S.A., Japan, and the U.K. are the premiere nations in this area.

7.1 Competitiveness in International Vaccine Development

The U.S.A. is by far the most active country in terms of number of companies involved in research and development of large animal vaccines (see Table 7.2). Several factors account for this including:

1. A large number of firms involved primarily in research into human vaccines, but also have an interest in the animal area for use as a test market, and to generate cash flow, since veterinary products can typically be brought to market more quickly.

2. Several smaller companies who began in the diagnostic area have used the knowledge gained in this area to expand into vaccines.

3. the U.S.A. represents the largest single country market for large animal vaccines, hence, there is opportunity for more companies to operate profitably.

Canada is reasonably well placed in this market, in that we have more firms/organizations active in this area than would be suggested, based on our demographics and are perceived to have a leading position in this area, even though the United States can and does "outspend" Canada from a relative perspective.

Our close proximity to the American market, traditional strength in the area of vaccines, and a few key individuals are the reason for the relative preponderance of research in this area.

Table 7.2 COMPANIES/INSTITUTIONS INVOLVED IN PRODUCTION/ MARKETING OF LARGE ANIMAL VACCINES USING BIOTECHNOLOGY

COUNTRY	# OF COMPANIES/ ORGANIZATIONS
Canada	8
U.S.A.	113
Europe	34
Japan	1

* Some double counting as some companies are active in more than one country

Europe countries and Japan are somewhat less involved in this area. In the case of most European countries and Japan, it is because other sectors, particularly human health, have been emphasized due to a perception that potential returns in agriculture are less lucrative, and in Japan, a large domestic production base on which to try out new products is lacking. Additionally, Japan was also perceived to be research-driven rather than market-driven in the animal production area. Research activity is undertaken in independent laboratories which can provide commercial opportunities for organizations which recognize the commercial potential for this research activity.

7.2 International Competitiveness in Biotech Animal Care Products

The number of organizations involved in research in biotechnology related to growth hormones is much lower than in vaccines, largely because of the cost and uncertainty of product development and registration, and to a certain extent, market and socio-economic concerns. Some 50 organizations are active in this field in the U.S.A.; 30 in Europe; and15 outside this area. Irrespective of the lower emphasis of U.S. firms/organizations in this area, the U.S. was still perceived to be "pulling away" in this area of research. The number of firms and organizations involved in probiotic biotechnology applications is not known at this time, but is much less than the above two areas. Europe, particularly the U.K. and Sweden, are

identified as having a lead position or profile in this activity. The Rowett Research Institute in the U.K. has a significant undertaking in this area.

In overall terms, that is, research and development activities in all biotechnology, the United States dominates the field with a total of 513 (64%) firms and organizations involved in this area (Table 7.3). Europe (185 - 24%), Japan (36 - 5%), Canada (26 - 3%) and Australia (18 - 2%) are the other major participants in this market.

TABLE 7.3 NUMBER OF COMPANIES INVOLVED IN ANIMAL AGRICULTURE RELATED BIOTECHNOLOGY

NUMBER OF FIRMS/ORGANIZATIONS

COUNTRY/REGION	#	%
U.S.	513	64
EUROPE (including U.K.)	185	24
U.K.	52	7
JAPAN	36	5
CANADA	26	3
AUSTRALIA	18	2
OTHER	26	3

7.3 Investment in Research and Development Activities

The level of investment in veterinary or animal agriculture is difficult to ascertain, given the heavy involvement of the major animal health product manufacturers in the human health sector as well as the veterinary sector. However, some indication of the relative or typical investment levels of firms specializing in specific areas in the United States, for example (Figure 7.1).

Typical R&D budgets are $2-4 million in 1987/88 with the exception of the therapeutics (human) area. Budgets were typically $10 million plus. There was also a high level of investment in therapeutics and plant agriculture relative to revenues, perhaps reflecting higher levels of expected returns or less risk.

7.4 International Overview of Government Role in Biotechnology

Government policy can have a major impact on the development of any industry. The biotechnology industry is particularly sensitive to the policy environment due to the long product development time horizons, high risk and massive need for information and capital. In particular, the following policy areas may have an impact on the rate of development of the sector:

- support of R&D
- fiscal measures
- tax and labour laws
- technology transfer
- industrial participation in policy decisions
- government funding of new companies
- regulation of biotechnology
- government pricing of both products and raw materials

Table 7.4 shows government involvement in biotechnology for most major countries. Involvement is noted in terms of support for basic research, applied R&D, and industrial

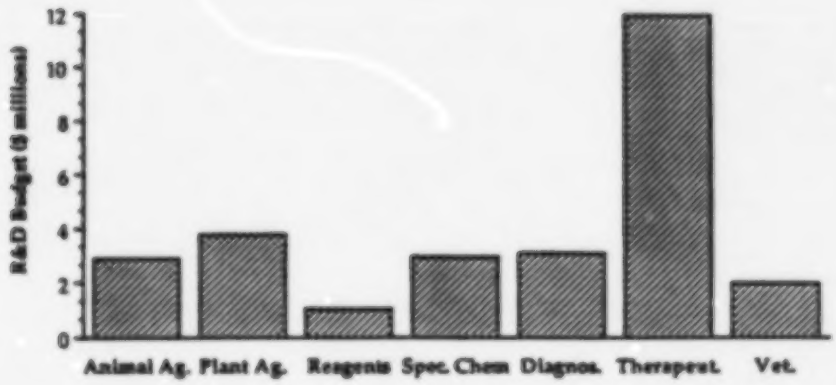
activities. This table shows that, of all major biotech producing countries (The U.S.A., Japan, Germany and The U.K.), all but the United States have significant public sector participation at all levels. Canada shows a reasonable level of support in the areas of basic research, and applied R&D, but does not appear to support industrial activities to the extent that Japan, and many European countries do.

Aside from direct funding, the U.S. Department of Commerce has identified an important roles for government in the acquisition and dissemination of biotechnology information including:

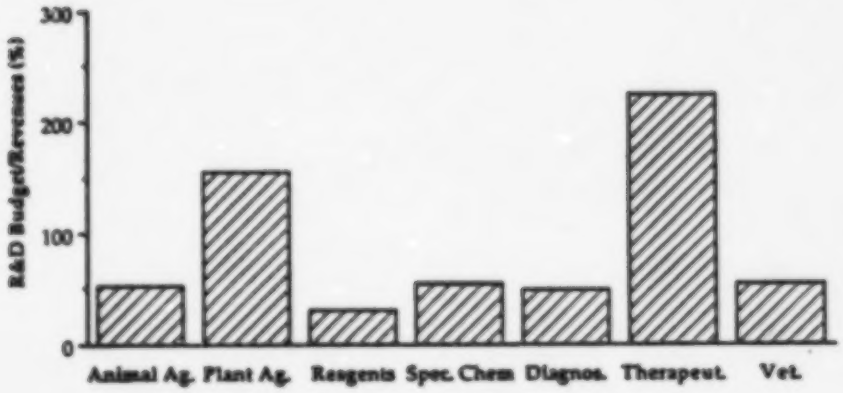
- DNA, RNA protein sequences;
- structural data on biological molecules;
- listings of microorganisms, plant and animal cell lines;
- patent registration and regulation.

Figure 7.1 U.S. Biotechnology Company R&D Budgets - by industry classification

A.



B.



A. The average R&D budget in millions of dollars is shown for U.S. biotechnology companies specializing in animal agriculture (4 companies), plant agriculture (17), reagents (13), specialty chemicals (14), diagnostics (30), therapeutics (33) or veterinary areas (6). Data are from mid-1987 to February 1988.

B. The average R&D budget, as a percent of revenues, is shown for the same groups of companies.

Table 7.4

THE ROLE OF GOVERNMENT IN BIOTECHNOLOGY

	Basic Research		Applied R&D			Industrial Activity		
	Research Funding	Research Institutes	Technology Transfer Institutes	Funding		Tax Credits	Loans/ Grants	Risk Capital
				Univ/Inst	Industry			
Finland	+		+					
Norway	+	+						
Italy	+			+	+			
Spain	+	+	planned	+	+		+	+
Switzerland	+		+ [1]	+/- [2]				
Denmark	+		+	+	+		+	
Sweden	+	+	+	+	+		+	+
Netherlands	+		+	+	+	+	+	+
France	+	+	+	+	+	+	+	
U.K.	+	+	+	+	+	+	+	+
Germany	+	+	+	+	+	+	+	+
Japan	+	+	+	+	+	+	+ [3]	+
U.S.	+	NIH			+	+		
Canada	+	+	+	+	+	+	+	

[1] Some activities at Swiss Federal Institute of Technology, Zurich

[2] Limited funding

[3] Development banks/low interest

Based on U.S. Department of Commerce

NIH - National Institute of Health

8.0 OVERALL ASSESSMENT OF MARKET ALTERNATIVES

A number of issues surface when considering long term investment in uncertain research and development, and high risk, volatile commercial ventures. That is, perhaps, more difficult when the basis for decision making is uncertain and speculative. One mechanism for doing this is to develop an appropriate weighting matrix for both the factors to be considered in the evaluation, and how individual products or groups of products fit on this particular feature.

One approach is seen in Chart 8.1 which shows an assessment made by the Technology Management Group for selected biotech product areas. An advanced and more specific approach, and one which can be used by individual industry participants to apply their own weighting, is shown in Chart 8.2. This evaluation framework incorporates thirteen commercialization or investment factors/criteria, including:

- Development Time
- Development Cost
- Availability of Canadian Biotech Resources
- Canadian Exploitation Potential
- Window of Commercial Opportunity
- Potential Benefits to Biotech Industries
- Sustainability of Competitive Advantage
- Potential Benefits to Canadian Livestock Producers
- Potential Margins for Product Type
- Potential Benefits of Supporting Industries (e.g., Distributors, Veterinarians, Suppliers)
- Negative Effects of Non-Development
- Sensitivity to Socio-Economic Environment Impacts, and
- Sensitivity to Regulatory Difficulties.

A specific weighting of relative importance was applied to each factor reflecting in a Deloitte and Touche assessment of the significance of the factor in the current Canadian context on a scale of 0 - 2. Subsequently, we applied an individual score to each of nine product areas, viz:

- dairy probiotic feed efficiency/performance/animal health product
- dairy product quality enhancement product
- cattle univalent vaccine
- cattle multivalent vaccine
- cattle probiotic feed efficiency/performance product
- cattle quality enhancement product
- hog scours univalent vaccine
- hog probiotic feed efficiency/performance product, and
- hog quality enhancement product.

These weightings were then used to develop a market attractiveness index (Chart 8.3) which results from the following calculation for each product:

$$\frac{\Sigma \quad \text{Factor Weight x Factor Rating}}{\Sigma \quad \text{Factor Weights}}$$

The market potential for these product areas developed in Chapter 4 (Table 4.4) can be compared with the market attractiveness index to provide a visual assessment of the potential Chart 8.4.

Obviously, it is debatable whether these are the real factor weights which should be used or realistic values for individual product potential or market assessibility weightings. However, they do show that there is perhaps greater potential for cattle-based products, given the numbers and potential value of these products. It also shows that product quality enhancement products, and vaccines are more attractive commercial prospects relative to probiotic products at the present time, based on the assessment formula used.

CHART 8.1 ATTRACTIVENESS OF SELECTED BIOTECH PRODUCT AREAS IN ANIMAL CARE

	Present Competition	Worldwide* Market Potential	Time to Commercial-ization
Recombinant Vaccines	significant	moderate	moderate
Growth Hormones	significant	moderate	moderate
Mab Diagnostics	significant	moderate to high	short to high
Interferons, Interleukins & other Lymphokines	moderate	moderate	moderate
Antibiotics	low	low	moderate
Feed Additives	significant	high	moderate
Reproductive Services	significant	low	short

Source: Technology Management Group 1986

* high: > $5 billion
moderate: $1 to $5 billion
low: $1 billion

CHART 8.2 EVALUATION FRAMEWORK FOR BIOTECHNOLOGY INVESTMENT

COMMER-CIALIZATION FACTOR	IMPLICATIONS FOR COMMERCIALIZATON OR COMPETITIVENESS	RATING SCALE	IMPORTANCE IN OVERALL COMPETITIVENESS	ASSESSED FACTOR WEIGHT 0 - 2
Development Time	Development time for exploratory research to commercialization 1- short development time 10- long development time	1-10	Need short term results -Important	1.0
Development Cost	Development cost incurred from exploratory research to commercialization. 1- relatively low cost 10- relatively high cost	1-10	Important that costs be reasonable and largely known-Important	1.25
Canadian Biotech Resources	Academic & Industrial Biotech research resources to transform to viable, marketable products. 1- low level of biotech resources 10- high level of biotech resources	1-10	Easier to develop and maintain momentum with existing technological capacity to continue to innovate and refine-Important	1.0
Canadian Exploitation Potential	Does Canada have marketing/distribution/ manufacturing infrastructure for domestic and international commercial exploitation 1- low level of exploitation potential 10- high level of exploitation potential	1-10	Very important to have capacity to bring products to world market.	1.4
Window of Opportunity	Opportunity for Canadian biotechnology to develop and maintain lead over international competition in an area of specialist expertise 1- short-term window of opportunity 10- long-term window of opportunity	1-10	Very important to be early in to get economic benefits that go to innovator. - margins decline over product life cycle.	1.6
Potential benefits to Biotech Industries	Potential for spin-off benefits in other biotech areas of research and commercial product development 1- low potential spin-off 10- high potential spin-off	1-10	Important consideration	1.0

COMMER-CIALIZATION FACTOR	IMPLICATIONS FOR COMMERCIALIZATON OR COMPETITIVENESS	RATING SCALE	IMPORTANCE IN OVERALL COMPETITIVENESS	ASSESSED FACTOR WEIGHT 0 - 2
Sustainable Competitive Advantage	Can products be easily duplicated, improved or substituted. 1- Weak sustainable advantage 10- Strong sustainable advantage	1-10	Important to get some market control to earn margins and returns to cover investment.	1.6
Potential benefits to Canadian farmers	Potential for increasing competitiveness of Canadian farmers/Is the issue eudemic to Canada 1-low benefits to Canadian producers 10- high benefits to Canadian producers	1-10	Politically more significant that	0.4
Potential margins of product type	High value (margin) products generally provide faster return and with less risk. 1- likely low margin products 10- likely high margin products	1-10	Perhaps most important attribute	2.0
Potential benefits to supporting industries	Spin-off benefits to supporting industries eg. distributors, retailers, vets, suppliers 1- low spin-off benefits 10- high spin-off benefits	1-10	Important component but supporting industries will likely survive regardless	0.2
Negative effects of non-development	Likely costs of non-development on biotech industry or domestic livestock production 1- high cost of non-investment 10- low cost of non-investment	1-10	Important that biotech industry not lose momentum, prestige but less important in long run	0.2
Socio-economic environment	Level of socio-economic resistance or costs to research, product introduction or commercial development 1- high socio-economic resistance 10- low socio-economic resistance	1-10	Important long term consideration	0.8
Regulatory Influence	Regulatory uncertainty, costs and time for registration of new product 1- high regulatory uncertainty 10- low regulatory uncertainty	1-10	Important consideration but int'l competition will likely face similar environment	0.2

CHART 8.3 BIOTECHNOLOGY MARKET OPPORTUNITY ASSESSMENT EVALUATION FRAMEWORK

	DEV'MENT TIME	DEV'MENT COST	CANADIAN BIOTEC RESOURCES	CANADIAN EXPLOIT'N POTENTIAL	WINDOW OF OPP'TUNITY	SUSTAINABLE COMPETITIVE ADVANTAGE	BENEFITS CANADIAN FARMERS
	product rating (1 - 10)						
DAIRY(Probiotic)	2	6	1	2	5	4	3
DAIRY(Quality Enhancement)	4	2	2	2	4	9	8
CATTLE(IBR/UNIVALENT)	6	6	4	3	4	3	5
CATTLE(/MULTIVALENT)	6	4	4	3	4	4	6
CATTLE(Probiotic)	2	6	1	2	5	4	3
CATTLE(Quality Enhancement	4	2	2	2	3	9	8
HOGS(SCOURS/UNIVALENT	6	6	4	3	4	3	5
HOGS(Probiotic)	2	4	1	2	5	4	3
HOGS(Quality Enhancement)	4	2	2	2	3	9	8

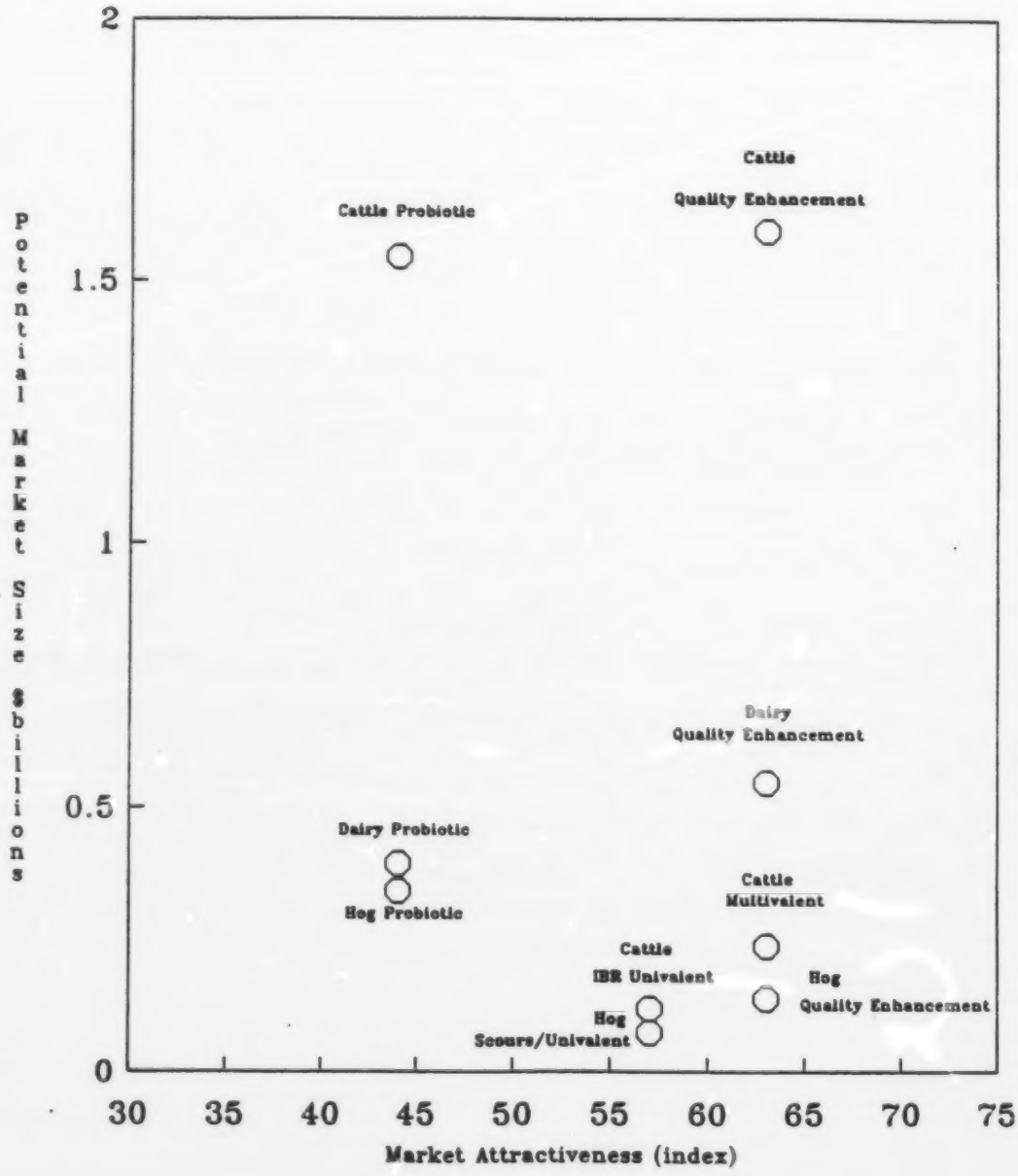
1 = relatively poor rating

10 = relatively good rating

CHART 8.3 BIOTECHNOLOGY MARKET OPPORTUNITY ASSESSMENT EVALUATION FRAMEWORK

	BENEFITS CANADIAN BIOTEC INDUSTRY	BENEFITS TO OTHER CANADIAN INDUSTRY	NEGATIVE IMPACTS OF NON DEVELOP'T	SENSITIVITY TO SOCIO- -ECONOMIC ENVIR'MENT	REGULATORY REQUIRE'TS	POTENTIAL MARGINS	MARKET ATTR'NESS INDEX
DAIRY(Probiotic)	4	3	3	8	2	3	44
DAIRY(Quality Enhancement)	7	5	5	2	4	8	63
CATTLE(IBR/UNIVALENT)	6	4	7	7	6	5	57
CATTLE(/MULTIVALENT)	7	4	7	7	6	6	63
CATTLE(Probiotic)	4	3	3	8	2	3	44
CATTLE(Quality Enhancement	7	5	5	3	4	8	63
HOGS(SCOURS/UNIVALENT	6	4	7	7	6	5	57
HOGS(Probiotic)	4	3	3	8	2	3	44
HOGS(Quality Enhancement)	7	5	5	3	4	8	63

CHART 8.4 MARKET ATTRACTIVENESS ASSESSMENT OF POTENTIAL BIOTECHNOLOGY PRODUCTS (GLOBAL SCALE)



APPENDICES

APPENDIX 4.1

List of Participants in Animal Health Product Research and Development Manager Survey

1. Elanco, Division of Eli Lilly, Indianapolis, U.S.A.
2. Monsanto, St. Louis, U.S.A.
3. Syntex Animal Health, Mississauga, Canada
4. Hoechst Canada Inc., Regina, Canada
5. Hoechst Roussel, Agri-Vet Company, Sommerville, N.J., U.S.A.
6. Pfizer Canada, Montreal, Canada
7. Upjohn Animal Health, Kalamazoo, Michigan, U.S.A.
8. Janssen Pharmaceuticals Inc., Mississauga, Canada
9. Pitman Moore, Chicago, U.S.A.
10. Sanofi, Cambridge, Ontario, Canada

APPENDIX 4.2

Components of the Adoption/Discussion Model

Stages of Adoption:

1. **Awareness.** The individual learns of the existence of the new idea or innovation, but lacks information about it;

2. **Interest.** The individual develops interest in the innovation and seeks additional information about it.

3. **Evaluation.** The individual makes mental application of the innovation to his present and anticipated future situation and decides whether or not to try the innovation;

4. **Trial.** The individual actually tries the new idea on a small scale in order to determine benefits to his/her own situation; and

5. **Adoption.** The individual uses the new idea continuously on a full scale.

The above is an extremely useful model for investigating the development and adoption of new products and technologies. A feature of this model is that adoption can not be automatically assumed to occur even though a specific need has been identified. Rather, for some products, the time duration between awareness and adoption may be a matter of years versus months.

Similarly, the factors which can affect the rate and level of adoption include:

Relative Advantage. The advantage of an innovation relative to the existing technology package is a strong determinant of successful adoption.

Measurability. The probability of someone adopting a technology will increase if the benefits, or relative advantage is easily measured.

Compatibility. This concept relates to the extent the innovation is consistent with existing management practices and experience. As well it can relate to the compatibility with the

existing complementary inputs.

Complexity. New techniques and innovations and their consequences can be difficult or easy to understand. Less complex ideas are more quickly and widely adopted.

Divisibility. This applies to the extent that an innovation can be applied on a limited scale within an enterprise. Divisibility limits exposure and risk.

Reversibility. Can individuals who are dissatisfied with the product readily reverse to the prior management practice or product with, at most, only minor cost adjustments.

Additive/Substitutes. Some products are additions (complements) to existing technology packages, while others are substitutes for current technology packages. Adoption is relatively easier when the new technology is an addition to current practices.

Communicability. The knowledge and information concerning some technologies can be communicated to potential users more easily than with others. This concept incorporates some dimensions of the complexity of an innovation and as well the tangibility of benefits.

Age of Innovation. A newer innovation is less likely to be adopted by the majority than an older innovation. This results directly from the innovation process where for many individuals a longer period of time is required to gather interest, evaluate the product and conducts some trails.

Initial Investment Required. A low initial investment will be more conducive to adoption than a high initial investment. This investment can be measured in terms of capital outlays, time invested to acquire information and manage a new innovation. This stems directly from the potential risks associated with the product and opportunity costs of time and money.

APPENDIX 4.3

Feed Efficiency Enhancement

The value of increased feed efficiency to the Canadian swine industry of a probiotic to enable the use of alfalfa in swine rations was calculated to be $59 million. The major benefit to the using alfalfa is the cost of protein. Current production practices call for the use of barley or corn as the basic hog ration, supplemented by either soybean or canola meal to achieve the needed protein content. Both soybean and canola meal have high protein contents, but are relatively expensive as well. Table 4.3 shows the cost per kg of protein for various feed ingredients, based on 1988 average prices.

Table 4.3 Protein Costs from Major Feed Ingredients

FEED INGREDIENT	DIGESTIBLE PROTEIN - % AS FED	FEED COST $ PER TONNE (1988)	PROTEIN COST $ PER KILOGRAM
ALFALFA	16	85	.53
BARLEY	8.9	105	1.18
CORN	6.8	101	1.48
48% SOY MEAL	43.7	354	.81
WHEAT	12.8	130	1.02

In calculating the value of alfalfa as an alternative source of protein several assumptions were made regarding the efficacy of potential probiotics. These assumptions were made following discussions with researchers active in this area. The assumptions are:

1. the probiotic will enable the hog to digest 80% of the available protein and energy;
2. that dehydrated alfalfa pellets will be used, and consumption will not be limited by bulk; and
3. hogs under 25 kg's will not be fed a probiotic.

Rations costs were calculated and balanced for total protein, lysine, and available energy utilizing a least cost optimization computer program, comparing a corn/soymeal ration with one which contains alfalfa. The results, and the cost savings per tonne of feed to using alfalfa

are shown in Tables 4.4 and 4.5. Prices and ration components were based on South-western Ontario, 1988.

Table 4.4 Ration Components and Costs, With and Without Alfalfa

Type of Ration	Ingredient	With Alfalfa	Without Alfalfa
		Kg/tonne of complete feed	
Grower (16% protein)	alfalfa	252.7	0
	corn	530.9	718.5
	soymeal	196.4	261.5
Finisher (14% protein)	alfalfa	277.2	0
	corn	568.7	775.3
	soymeal	134.0	205.0
Sow and boar ration	alfalfa	289.5	0
	corn	587.6	802.5
	soymeal	102.9	177.5

Table 4.5 Ration Costs, With and Without Alfalfa

Ration	Cost With Alfalfa ($ per Tonne)	Cost Without Alfalfa ($ per Tonne)	Savings ($ per tonne)
Grower	140.60	151.60	11.00
Finisher	132.25	144.31	12.06
Sow & Boar	128.08	140.67	12.59

If these feed cost savings are assumed to be equal across Canada, then the potential benefit to the industry can be calculated by multiplying the feed cost savings by the average feed consumption per hog and the average number of hogs marketed in Canada per year. The market potential by type of feed is shown in Table 4.6.

Table 4.6 Probiotic Market Potential - by Type of Feed

Type of Feed	Market Potential ($ million)
Grower	8,772
Finisher	34,220
Sow and Boar	16,112
TOTAL	59,105

The figure shown in Table 4.6 represent the maximum potential based on the increase in feed cost efficiency from using alfalfa in swine rations. The actual market would be somewhat less than this due to the fact that many farmers would be reluctant to switch based on their own specific circumstances.

Health Status Improvement

It is very difficult to assess the financial benefits of feeding alfalfa from a health standpoint as quantitative studies have not been undertaken. It is recognized that increasing fibre in swine diets can have several beneficial effects, particularly with pregnant and lactating sows. These are:

1. Reducing the incidence of stereotypy. Stereotypy is a type of abnormal behaviour characterized by a constant, almost mechanical repetition of the same movement. In itself, it is not life threatening, but is the first sign that the animal is under stress. In this condition, a sow can spend up to 15% more energy a day in performing these mindless movements, which translates to less energy being spent providing nutrition to her piglets. One theory for the cause of stereotypes is hunger, by increasing the fibre content of feed, it is hoped that a "full feeling" may be maintained, and the level of frustration will be reduced.

2. Mastitis Metritis Agalactia (MMA). MMA is partly caused by toxins released in the digestive tract and results in an inflammation of the mammary glands. Lactating sows with MMA will produce little or no milk at all, forcing the producer to move newborn piglets to another nursing sow. Increasing the fibre in a sows diet should help to remove the toxins from the animals system before they have the chance to do any

harm.

Because the research on impacts of feeding higher proportions of fibre in swine diets is not complete from an animal health standpoint, for this market assessment we will not assess a market value from animal health benefits, but will assume that adoption will occur somewhat early due to these beneficial side effects.

Increased Demand for Alfalfa

Alfalfa is a crop that is grown in virtually all regions of Canada, with the exception of the brown soil zones of the prairies. The crop is almost always grown for local use in livestock operations. Alfalfa is a very important crop from a rotational point of view. As a legume it is capable of fixing nitrogen and building soil fertility, and as a deep rooted perennial it has benefits in terms of conserving soil and maintaining or enhancing soil structure. Currently, few swine farmers are able to grow this crop due to a lack of usage opportunities on farm, and the lack of a consistent cash market. The ability to utilize alfalfa on farm would have significant benefits from a soil management point of view.

Economic research conducted by Deloitte & Touche on behalf of Agriculture Canada has shown that, over a twenty year time span, the potential benefits of an alfalfa/corn crop rotation compared to continuous corn could be up to $75 per acre per year, in terms of increased productivity. If the market potential mentioned above were realized, a total of 4.9 million tonnes of alfalfa per year would be required. At 2.7 Tonnes per acre, this would mean that 1.8 million acres of alfalfa would be required. If a benefit of $25 per acre is used (to compensate for the fact that not all of the crops replaced would be continuous corn), then the total benefit could be as high as $45 million per year in increased soil productivity.

SOMMAIRE ET CONCLUSIONS

ÉTUDE DE POSSIBILITÉS STRATÉGIQUES POUR LA BIOTECHNOLOGIE CANADIENNE DANS LE SECTEUR DES PRODUITS DE ZOOTECHNIE

Rapport de la deuxième étape
Deloitte & Touche, janvier 1991

SOMMAIRE ET CONCLUSIONS

Le ministère de l'Industrie, des Sciences et de la Technologie (ISTC) cherche à déterminer des possibilités stratégiques pour le Canada en matière d'application de la biotechnologie aux animaux. Il a demandé à la société Deloitte & Touche de préciser et de caractériser les créneaux les plus efficaces dans le domaine de la biotechnologie animale. Un rapport initial de la Phase I fait état de 11 mécanismes biotechnologiques qui pourraient servir à mettre au point des produits susceptibles d'atteindre sept objectifs de production animale, comme l'amélioration de la productivité, l'efficacité des provendes, la qualité des carcasses et le contrôle des maladies.

Trois genres de produits ont été choisis parmi cet éventail important de possibilités, en vue d'un examen et d'une caractérisation plus détaillés de leur potentiel commercial ainsi que de leurs conditions de mise au point et de commercialisation.

Ces genres de produits sont les suivants :

- les vaccins univalents et polyvalents;
- les probiotiques;
- les techniques d'immunisation en vue de la qualité des carcasses.

La détermination des possibilités du marché comprenait une perspective globale mais mettait surtout l'accent sur les marchés nord-américains, européens et sud-américains des produits de biotechnologie animale. Les critères d'évaluation primordiaux en matière de mise au point de produits ont été les suivants :

i) la durée et le coût de la mise au point commerciale de produits éventuels;

ii) l'existence d'une biotechnologie canadienne et de possibilités d'exploitation commerciale (ressources nécessaires);

iii) la possibilité d'assurer et de maintenir l'avantage que constitue la compétitivité dans les domaines de la mise au point et de la commercialisation des produits;

iv) les avantages commerciaux et financiers possibles pour les sociétés canadiennes de biotechnologie, les agriculteurs canadiens et autres intervenants;

v) les répercussions défavorables de l'absence de compétences et de produits dans ce domaine de la biotechnologie;

vi) les conditions socio-économiques de la recherche sur les produits ainsi que de l'enregistrement et de l'utilisation de ces derniers.

L'évaluation des possibilités du marché et des conditions de mise au point de produits a nécessité l'examen et l'analyse de données et de renseignements publiés et non publiés sur les créneaux visés, ainsi qu'une série d'échanges de vues et de consultations avec les intervenants en matière de recherche biotechnologique et de commercialisation des produits biotechnologiques.